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GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION

In Support of the Massachusetts Contingency Plan

*** Chapter 9 ***

Method 3 Environmental Risk Characterization

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April 22, 1996

To All Interested Parties:

Attached please find the Environmental Risk Characterization section of the *Guidance for Disposal Site Risk Characterization*, the main body of which was published in July of 1995 as an Interim Final Policy WSC/ORS-95-141. As an Interim Final Policy, reviewers and users are encouraged to submit comments and recommendations for revision through December 1996. In the interim, however, the guidance may be used and cited as a reference in risk characterizations conducted to meet the requirements of the MCP.

This document was developed through the efforts of the Environmental Risk Characterization Workgroup, which is composed of ecological risk assessors from private consulting firms, U.S. EPA and Massachusetts Fish and Wildlife and Massachusetts DEP. Members of the Workgroup are listed in the Foreword of the Guidance for Disposal Site Risk Characterization. The Workgroup focused on technical and scientific issues critical to development of the guidance.

A number of policy issues remain under consideration, for example, questions related to the application of surface water standards at disposal sites. We expect that, as more environmental risk characterizations are conducted pursuant to meeting MCP requirements, we will revise this document to reflect the practical experience gained.

DEP is also establishing an "Environmental Risk Characterization Review Panel" (a subcommittee of the Waste Site Cleanup Program Advisory Committee) to review environmental risk characterization reports voluntarily submitted for the panel's evaluation and comment. Based on the Panel's recommendations and the experience of other users, we expect to re-evaluate and revise appropriate sections of the guidance. We hope that continued review and discussion will ultimately ensure that this document provides clear and practical guidance for conducting ecological risk characterizations.

Please direct any questions or comments on this document to Nancy Bettinger in DEP's Office of Research and Standards. Ms. Bettinger may be reached by telephone (617/556-1159) or electronic mail (nbettinger@state.ma.us).

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GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION

- IN SUPPORT OF THE MASSACHUSETTS CONTINGENCY PLAN

*** CHAPTER 9 ***

Method 3 Environmental Risk Charaterization

INTERIM FINAL POLICY
WSC/ORS-95-141

MASSACHUSETTS DEPARTMENT OF ENVIRONMENTAL PROTECTION

BUREAU OF WASTE SITE CLEANUP
and
OFFICE OF RESEARCH AND STANDARDS

April 1996

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GUIDANCE FOR ENVIRONMENTAL RISK CHARACTERIZATION

in Support of the Massachusetts Contingency Plan

Interim Final Policy #WSC/ORS-95-141

This document provides guidance for environmental risk characterization for disposal sites contaminated by oil and/or hazardous material. It is a component of *Guidance for Disposal Site Risk Characterization* (Interim Final Policy #WSC/ORS-95-141), which provides guidance for characterizing the risk of harm to health, safety, public welfare and the environment at disposal sites. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative proceeding with the Commonwealth. The regulations related to the characterization of risk of harm to the environment contain both specific and general requirements. In addition to summarizing specific requirements, this document also provides guidance on what approaches the Department considers acceptable for meeting the general requirements set forth in the regulations. Parties using this guidance should be aware that there may be other acceptable alternatives to this guidance for achieving compliance with such general regulatory requirements.

The regulatory citations provided throughout this document are not meant to be, and should not be relied upon to be, a complete list of all the regulatory requirements for risk characterization. Parties undertaking a risk characterization for a site should consult 310 CMR 40.0000 (MCP) for applicable requirements.

James C. Colman — 4/22/96

James C. Colman
Assistant Commissioner
Bureau of Waste Site Cleanup

Date

Carol Rowan West — April 22, 1996

Carol Rowan West
Director
Office of Research and Standards

Date

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9.0 METHOD 3 - ENVIRONMENTAL RISK CHARACTERIZATION

9.1 INTRODUCTION

The Massachusetts Contingency Plan ("MCP", 310 CMR 40.0000) requires a characterization of the risk of harm to health, safety, public welfare and the environment at all disposal sites, except where the site has been remediated to background levels. An Environmental Risk Characterization[1] is used to establish whether a level of "no significant risk of harm to . . . the environment" exists or has been achieved at a disposal site. The results of the environmental risk characterization provide information necessary to evaluate the need for remediation and to identify the applicable Response Action Outcome (RAO) for the disposal site.

9.1.1 Risk Characterization Methods

The MCP provides three approaches for characterizing risk at disposal sites, which are described at 310 CMR 40.0941. The first two are chemical-specific approaches (Methods 1 and 2), which compare site soil and groundwater concentrations to standards. The third is a site-specific risk characterization (Method 3), in which the risk characterization procedures take into account site-specific exposure patterns, contaminant distribution, and contaminant mixtures. This chapter of the guidance document focuses on site-specific environmental risk characterization. The chemical-specific approaches are explained in the human health risk characterization guidance (Sections 5.0 and 6.0).

The selection of the appropriate risk characterization approach is addressed in 310 CMR 40.0942 of the MCP and Section 3.0 of this document. As specified in that section, a Method 3 site-specific environmental risk characterization would be conducted in any of the following circumstances:

1. When the site-specific approach is used to assess human health risks, or

2. When the chemical-specific approach is selected to assess human health risks, but cannot be used for assessing environmental risk because of the existence of one of the following conditions:

 (a) oil or hazardous material is present in environmental media (such as surface water and sediment, including those media in wetlands), where nonhuman organisms are exposed, or may migrate to such media and potentially could reach concentrations resulting in significant exposures to organisms; or

[1] "Environmental Risk Characterization" is synonymous with "environmental risk assessment" and "ecological risk assessment". The latter terms are commonly used by other regulatory programs and agencies.

(b) substances known to bioaccumulate[2] are present within the top two feet of soil, and organisms likely to be exposed to surface soil contaminants have been identified at the site.

At sites where the chemical-specific approach is selected, a site-specific Environmental Risk Characterization will not be required, as long as neither of the two exclusions described under (a) and (b) in the previous paragraph applies. The process of selecting the appropriate risk characterization method is outlined in Figure 9.1.

9.1.2 General Risk Characterization Requirements

The MCP specifies two components of environmental risk characterization: (1) combining site-specific information on contaminant distribution, contaminant toxicity, and receptor exposure in a site-specific assessment of the risk of harm to habitats and biota from the oil and/or hazardous material (OHM) at or from the site; and (2) comparing contaminant concentrations in environmental media to Applicable or Suitably Analogous Standards and to the Upper Concentration Limits (UCLs) specified in the MCP. The second component is discussed further in Section 9.7. All other sections of this chapter address the site-specific characterization of risk to biota and habitats posed by oil and/or hazardous material (OHM) at (or from) a disposal site.

This guidance is structured so that, very early in the process, the ecological risk assessor will identify exposure pathways unlikely to pose significant risk of harm, and rule out the need for further detailed quantitative assessment of those pathways. To facilitate the elimination of insignificant exposure pathways from extensive assessment procedures, the MCP divides the Environmental Risk Characterization process into two stages: Stage I Environmental Screening and Stage II Environmental Risk Characterization.

9.1.3 Stage I Environmental Screening

The overall purpose of a Stage I Environmental Screening is to evaluate the need for a quantitative Stage II Environmental Risk Characterization. **Stage I is used to eliminate from further evaluation those situations in which either (1) the exposures are clearly unlikely to result in environmental harm or (2) harm is readily apparent.** Exposure pathways that are not eliminated in Stage I are carried through the quantitative Stage II Environmental Risk Characterization process.

[2] Substances known to bioaccumulate include, but are not necessarily limited to, mercury, cadmium, PCBs and pesticides (See MCP Q&A Special Edition #4, February 1995).

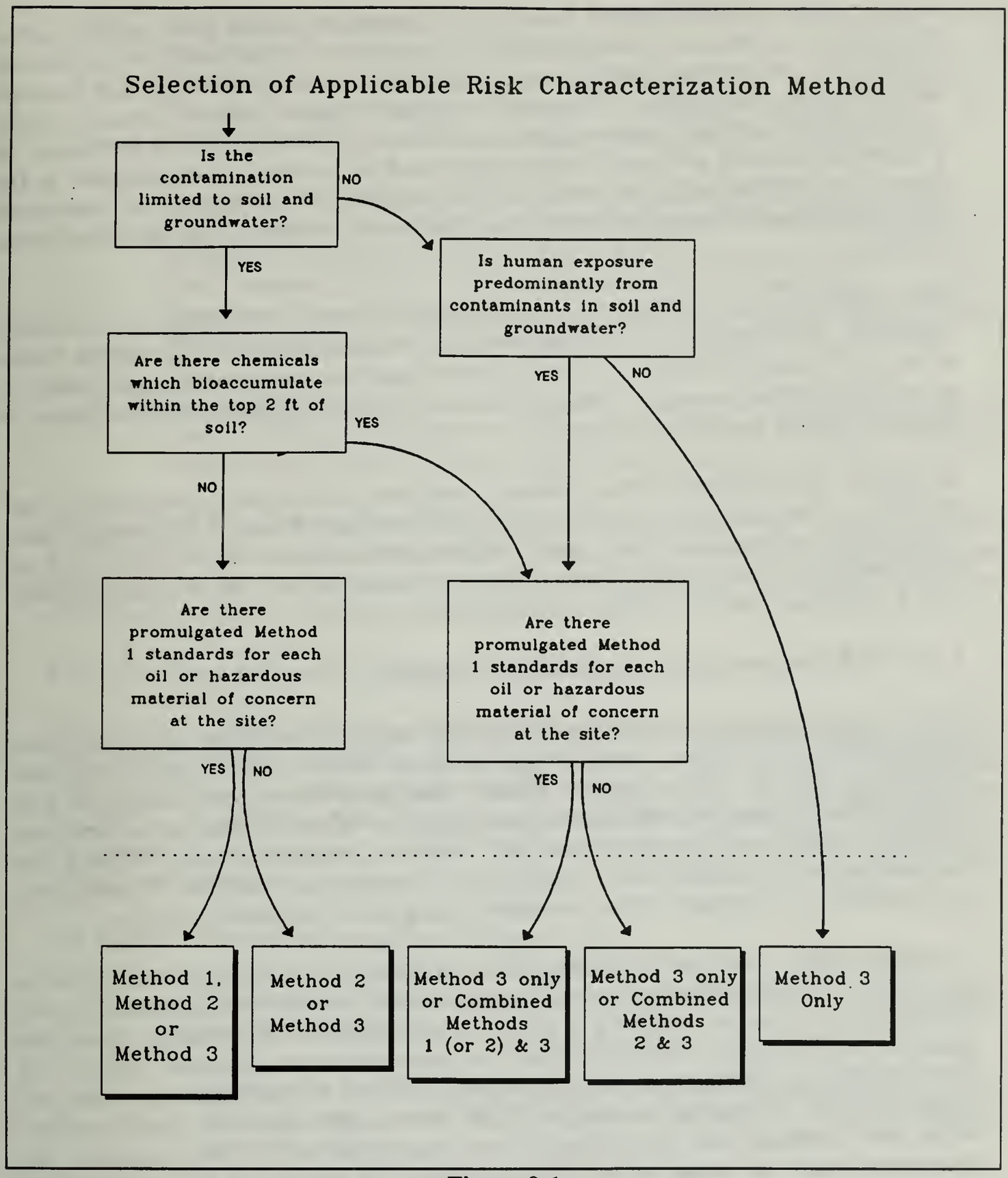

Selection of Applicable Risk Characterization Method
Is the contamination limited to soil and groundwater?
NO
YES
Is human exposure predominantly from contaminants in soil and groundwater?
YES
NO
Are there chemicals which bioaccumulate within the top 2 ft of soil?
YES
NO
Are there promulgated Method 1 standards for each oil or hazardous material of concern at the site?
YES
NO
Are there promulgated Method 1 standards for each oil or hazardous material of concern at the site?
YES
NO
Method 1, Method 2 or Method 3
Method 2 or Method 3
Method 3 only or Combined Methods 1 (or 2) & 3
Method 3 only or Combined Methods 2 & 3
Method 3 Only

Figure 9.1

In Stage I, the available evidence is evaluated to determine whether plants and/or animals are currently exposed, or could potentially be exposed, to contamination at or from the disposal site. An exposure pathway is a link between a contaminant source and receptors such as plants and animals. The term "complete exposure pathway" means that the contamination is *actually* reaching plants or animals, or is likely to do so in the future. **If a potential exposure pathway is not complete and is not likely to be complete in the future, hypothetical risks postulated for that pathway do not have to be considered further and do not have to be carried through the environmental risk characterization process.**

Each complete exposure pathway is evaluated in Stage I to determine whether it is potentially significant. If a significant risk of harm can readily be ruled out, it is not considered further in the risk characterization. Procedures for determining the potential significance of exposure pathways in aquatic, terrestrial and wetlands environments are recommended in Sections 9.4, 9.5 and 9.6, respectively.

In Stage I, any complete exposure pathways associated with "readily apparent harm" are identified. Conditions that constitute "readily apparent harm" include visibly stressed biota, contaminant concentrations that exceed environmental standards and visible oil or tar distributed over an area of soil greater than two acres or over an area of sediment greater than 1,000 square feet (310 CMR 40.0995(3)(b)1.).

9.1.4 Risk Characterization/Remediation Sequence

Risk characterization may be performed at any point during investigation and cleanup when sufficient data is available. Site investigators do not need to follow a rigid, sequential assessment process. **Like human health risk assessment, environmental risk characterization may be conducted either before or after remediation** to determine whether a condition of "No Significant Risk" exists or has been achieved. When a risk characterization is conducted prior to remediation, it is considered a baseline risk assessment, and it should not incorporate exposure reduction achieved by temporary measures.

In general, DEP recommends conducting the environmental risk characterization prior to remediation. However, the Department recognizes that it is often most appropriate to take remedial action prior to completing a full risk characterization. In particular, Immediate Response Actions (IRAs; 310 CMR 40.0410) or Release Abatement Measures (RAMs; 310 CMR 40.0440) are often taken prior to performing a full risk characterization to reduce risk to human health. However, site managers (DEP site managers and LSPs) should carefully weigh the advantages and disadvantages when planning to conduct environmental risk assessments after, rather than before, cleanup activities. A few reasons for caution follow:

1. A substantial amount of chemical and biological data are often needed for an environmental risk assessment. If a risk assessment is conducted prior to remediation, the sampling plan can be constructed so that the chemical analyses done for the assessment can also be used to develop the remediation plan. Post-remedial sampling for confirmatory purposes may then be relatively limited.

 If, on the other hand, the risk assessment is conducted after remediation, chemical samples needed for toxicity tests or field surveys must be collected after remediation, regardless of how well the site was characterized before cleanup. Such sampling is likely to be extensive relative to confirmatory sampling. Therefore, this sequence may require more extensive chemical analysis than is when the risk assessment is done prior to remediation.

2. The remediation activities themselves may disrupt ecological processes in the vicinity of the site, causing harm that may be incorrectly attributed to chemical contamination if the assessment is done after remediation, rather than before.

These cautions are offered to help DEP project managers, Licensed Site Professionals (LSPs) and Potentially Responsible Parties (PRPs) to implement a site assessment/management strategy that is the most efficient and effective in the long term. It is *not* DEP's intent to discourage expedited cleanup projects.

9.1.5 Guidance Document Objectives

This guidance draws heavily from the EPA's Framework for Ecological Risk Assessment (EPA 1992a) and from other EPA guidance (EPA 1989a, and EPA Region I 1989), with the intent of supplementing EPA guidance to clarify its applicability at 21E sites regulated under the MCP. It describes how DEP's objectives should be considered in planning an environmental risk assessment, and how the assessment results should be used to make remediation decisions.

The specific objectives of this guidance document are:

1. To identify the regulatory objectives contained in the MCP for environmental risk characterization;

2. To provide a framework for designing, conducting and interpreting the results of environmental risk characterizations pursuant to MCP regulatory objectives; and

3. To indicate the level of effort considered by the Bureau of Waste Site Cleanup (BWSC) to be appropriate for various types of sites.

This guidance is not a "how to" manual. It does not include specific test protocols, nor does it direct the risk assessor toward specific assessment activities that would be considered appropriate or necessary at any particular site. Instead it provides a general framework for using scientific knowledge and technical expertise to design and conduct investigations to meet MCP requirements. To ensure that risk assessment activities are coordinated with other sampling and analysis efforts, all project managers (DEP project managers or LSPs) should refer to this guidance in the early stages of project planning, and the overall investigation plan should be developed in cooperation with the risk assessor(s). While this guidance suggests many factors that should be considered in designing and conducting an ecological risk assessment, it cannot provide all the knowledge necessary to conduct such an assessment. Extensive professional judgment will be required to carry out these investigations. Thus, Stage II Environmental Risk Characterizations should always be conducted by individuals with extensive ecological risk assessment experience, although, in many cases, Stage I Screening can be conducted by environmental professionals who are not expert in ecological risk assessment.

This guidance has been developed for use in MCP risk assessments only. It is not intended for application to other regulatory programs. Many portions of this guidance are based on the program and policy objectives of BWSC. For example, the screening criteria recommended in this document mean that quantitative risk characterization will be applied at a small subset of all sites, and that those characterizations will focus on a small subset of all potential effects.

Part of the reason for this narrow focus is the recognition that some potentially adverse environmental impacts of OHM at or from disposal sites cannot be assessed and remediated effectively through the Waste Site Cleanup Program, which is designed to address impacts *on a site-by-site basis*. Cumulative effects of OHM at or from numerous waste sites are examples of impacts that cannot be accurately quantified in an individual site assessment, although the cumulative effects of some substances may be significant. Thus, the narrow focus of the assessment procedures described in this document should not be interpreted as an indication of what kinds of impacts DEP considers significant in general.

9.1.6 Relationship of Environmental Risk Characterization to Natural Resource Damage Assessments

Method 3 Environmental Risk Characterizations conducted to meet the requirements of the MCP often have components in common with evaluations conducted to support Natural Resource Damage Assessments (NRDAs). Environmental Risk Characterization is a basic component of site investigation under the MCP, and is required at all 21E sites. Natural Resource Damage Assessments are a separate process directed by state and federal agencies designated as Trustees; they are conducted at a relatively small subset of 21E sites. When both types of assessments are conducted at one site, there is a substantial overlap in data

requirements, and many data collection and analysis activities can be used for both types of assessments. In cases where both types of assessments are being conducted, coordination of efforts can be beneficial to both the regulatory agencies and the responsible parties.

Collaboration between NRD assessors and risk assessors can improve the overall economy of data collection and analysis. Coordinated prior planning can minimize duplication of efforts and maximize the useability of data for both purposes. Increased efficiency will benefit both the agencies and the responsible parties involved.

Beyond improving efficiency, collaboration with NRD risk assessors brings more extensive expertise to the process of planning, executing and evaluating an MCP risk assessment. Natural Resource Trustees include the Department of Interior (DOI), the Massachusetts Executive Office of Environmental Affairs (EOEA) and the National Oceanographic and Atmospheric Administration (NOAA). These agencies have staff with expertise in biology, ecology and ecotoxicology, whose knowledge and experience complements DEP staff expertise. Similarly, the DEP Project Manager's detailed knowledge and understanding of the site can be invaluable to the Trustees. Cooperation can strengthen both the MCP Environmental Risk Characterization and the Natural Resource Damage Assessment.

Coordination of efforts with Natural Resource Trustees, however, should not alter the scope or focus of the MCP risk assessment. In spite of substantial overlap in data requirements, it is important to recognize that the objectives and application of risk assessments done to meet the requirements of the MCP differ from those of Natural Resource Damage Assessments. Environmental Risk Characterizations are conducted to determine whether there is a ***risk*** of harm that warrants remedial action at a 21E site. In contrast, a Natural Resource Damage Assessment is a process by which natural resource ***injuries*** are determined and compensation is sought for lost resources. Specific examples of differences between the two types of assessments are discussed in the following paragraphs.

One basic difference between MCP risk characterizations and NRD assessments is the questions they address. NRD assessments focus on *observable* harm and past and/or present loss of resources. Risk assessments, on the other hand, are concerned with the *potential* for harm, both at present and in the foreseeable future. Risk assessments often evaluate subtle impacts on population health or community balance which cannot be measured directly. The potential for such subtle effects may be determined by extrapolation, about which there may be substantial uncertainty. Such an extrapolation may not provide a sufficient basis for an NRD case; thus, a risk characterization could conclude that there is a significant risk at a site where natural resource damages are not identified. The difference in the nature of the questions being addressed means that MCP risk characterizations and NRD assessments are likely to use data in different ways.

Another difference between Environmental Risk Characterizations and Natural Resource Damage Assessments is that they often focus on different kinds of resources. Natural Resource Damage Assessments typically focus on resources which have intrinsic societal value. Examples are fisheries, shellfish beds, migratory birds, endangered species and useability of recreational areas. In contrast, environmental risk assessments often focus on entities that have value because of their function in a natural community rather than direct use by people. One example is benthic invertebrates that are important as a prey base for other aquatic organisms.

Finally, some components of the MCP Environmental Risk Characterization procedures recommended in this document may not apply to NRDAs. In particular, the screening criteria and procedures outlined here are expected to eliminate substantial numbers of sites from further assessment requirements under the MCP. However, there may be situations where action is not required under the MCP, but where a Natural Resource Damage Assessment is appropriate and necessary. Nothing in this guidance document limits the regulatory or procedural requirements of the Natural Resource Damage Assessment process, or those of any other program.

The differences and the commonalities between risk assessments and damage assessments should be considered in the planning stage of both processes, so that data acquisition and analysis can be accomplished as efficiently as possible. The risk characterization and NRDA should be conducted separately, however, because the objectives are entirely different. Further, to avoid confusion about how the data is used in each type of assessment, Environmental Risk Characterizations and NRDAs should be documented in separate reports.

9.1.7 Outline of the Remainder of Section 9.0

Section 9.2 discusses general risk assessment considerations, including regulatory objectives and implementation goals. Section 9.3 outlines the Environmental Risk Characterization process and provides a framework for designing and conducting site- specific risk assessments. Assessment methods for aquatic, terrestrial and wetland habitats are discussed separately in Sections 9.4, 9.5 and 9.6. These topics are treated separately because the information and assessment techniques available for different types of habitats varies widely.

9.2 GENERAL RISK CHARACTERIZATION CONSIDERATIONS

9.2.1 Regulatory Objectives of Environmental Risk Characterization

The objective of an MCP Environmental Risk Characterization is to characterize the *risk of harm* to *habitats and biota exposed to OHM* at or from a disposal site. The phrases in italics represent key components of DEP's objectives with respect to sites. These are discussed below in more detail:

Risk of harm, and not proof of harm, is the central question in an MCP Environmental Risk Characterization. Proving or disproving that a disposal site has caused harm to the environment could require direct evidence from a rigorous quantitative field study that is generally beyond the scope of Environmental Risk Characterizations performed pursuant to Chapter 21E. The "risk of harm" standard, which has been established by Chapter 21E and codified in the MCP, relies upon available evidence to determine the likelihood of actual or potential impacts. Furthermore, "proof of harm" could only be obtained for past and possibly current exposures. It is impossible to prove or disprove potential future harm.

Habitats and biota exposed to OHM are the focus of MCP Environmental Risk Characterizations. Risks are evaluated for the subpopulations and communities that are actually or potentially exposed to contaminants at or from a site. The spatial scale of impacts from 21E sites is generally small, and in many cases, the scale is not much larger than the area of the site itself. Entire populations or ecosystems are seldom, if ever, impacted by a single 21E disposal site. MCP Environmental Risk Characterizations, like human health risk assessments, should focus on the subpopulations and communities that experience or could experience exposure.

The MCP (310 CMR 40.0995) states that four criteria must all be met in order to demonstrate that a condition of "no significant risk of harm to the environment" exists or has been achieved:

1. there is no physical evidence of a continuing release of oil and/or hazardous material at or from the disposal site to surface waters and/or wetlands which significantly affects environmental receptors; and

2. there is no evidence of biologically significant harm known or believed to be associated with current or foreseeable future exposure of wildlife, fish, shellfish or other aquatic biota to oil and/or hazardous material at or from the site; and

3. concentrations of oil and/or hazardous material at or from the disposal site do not and are not likely to exceed Massachusetts Surface Water Quality Standards as promulgated at 314 CMR 4.00 (and as amended) at current and reasonably foreseeable exposure points; and

4. there is no indication of the potential for biologically significant harm to environmental receptors, considering their location and the fate and transport characteristics of the oil and/or hazardous material at or from the site, currently or for any foreseeable period of time.

The regulatory objectives embodied in items (1) and (3) are fairly self-explanatory, and are not discussed further in this section. The objectives of items (2) and (4) are less straightforward. "Evidence of biologically significant harm" and the "potential for biologically significant harm" must be determined by conducting a risk characterization.

The "potential for biologically significant harm" may exist due to either (1) the possible effects of ongoing or past exposures or (2) the possibility that contaminant distribution may change in the future. Both current and future site conditions should be considered. Current conditions should be characterized in any case. Future conditions should be evaluated if contaminant fate and transport processes are likely to change the nature and distribution of contamination so that future exposures could differ from current exposures, particularly if contaminant concentrations could increase at any exposure points.

The phrase "biologically significant harm" as used in this document may mean an adverse effect at any level of biological organization, including organism, population, community and ecosystem level effects. Thus, the term applies to the organisms and groups of organisms that are components of an ecosystem as well as to the ecosystem as a whole. Although ecosystem level effects are often an underlying concern of environmental protection laws and regulations, they are not always measurable or predictable, and they often do not, in and of themselves, provide sufficiently sensitive indicators of environmental harm or risk posed by individual sites.

9.2.2 Implementation Goals

Like the human health risk assessment guidance, the MCP Environmental Risk Characterization guidelines are intended to be flexible, and to foster expedited site assessment/remediation projects. Toward that end, this guidance incorporates three major themes:

1. **Quantitative risk characterizations should be conducted at the sites most likely to pose a significant risk of harm to the environment, and are not necessary at sites where a significant risk of harm to the environment is unlikely.** The

Stage I Environmental Screening steps outlined for terrestrial, aquatic and wetland habitats are designed to enable site managers to determine relatively quickly and easily whether a Stage II Environmental Risk Characterization is warranted.

2. **When a Stage II Environmental Risk Characterization is warranted, it should focus on effects that are known to be caused by the contaminants at the site, and that could potentially be significant, given the possible exposures.** The *nature* of contamination found at a site determines the range of effects on which the assessment could potentially focus. The *extent* of contamination and the current and foreseeable exposures at the site determine which of those effects is likely to serve as a sufficiently sensitive indicator of risk at the site. Section 9.3.2.1 on Problem Formulation discusses selecting the effects on which the risk characterization should focus.

3. **The level of detail of any risk characterization should be tailored to the site in question.** Among different sites, the complexity of risk characterizations is expected to vary over a wide range. The appropriate complexity depends upon many factors, including, but not limited to, the number of contaminants and exposure pathways that must be evaluated and the quantity and quality of toxicity information available for the contaminants present. Section 9.3.2.1 on Problem Formulation discusses selecting the measurement methods appropriate to evaluate the effects of concern.

9.2.3 Possible Outcomes of an MCP Environmental Risk Characterization

The MCP describes categories of site conditions that can result from the investigation and cleanup process. These categories are called Response Action Outcomes ("RAOs") and are described in 310 CMR 40.1030 through 40.1050 of the MCP. The applicable RAO for a specific site depends on three factors: (1) the conclusions of the risk characterization; (2) the extent of remediation conducted at the site; and (3) the implementation of Activity and Use Limitations, which are sometimes necessary to achieve and maintain a condition of no significant risk.

There are two possible conclusions from a Stage II Environmental Risk Characterization. The first is a conclusion that no significant risk of harm to the environment exists or has been achieved at the site. In this case, no further remediation to protect environmental receptors would be required. A Class A or B Response Action Outcome (RAO) could apply, depending on whether remedial actions have been taken to mitigate site risks. A Class B RAO applies when a condition of no significant risk of harm to health, safety, public welfare or the environment exists at a site, and no cleanup is required.

The alternative outcome is a conclusion that a significant risk of harm to the environment exists, and, therefore, that remedial action must be implemented if feasible[2]. If remediation reduces levels of oil and hazardous material to background concentrations, a Class A-1 Response Action Outcome applies. If, on the other hand, contamination is remediated to a level of no significant risk, but not to background levels, a Class A-2 Response Action Outcome applies. If remediation to a condition of no significant risk is not feasible, a Class C Response Action Outcome applies.

9.2.4 Identification of Cleanup Goals

If significant risk of harm to the environment exists, and remediation is required to protect non-human receptors, then ecologically-based cleanup goals may be needed. If so, it may be more efficient to obtain the data needed for cleanup goals in the course of risk characterization, rather than afterward. For example, one way of identifying levels that pose no significant risk of harm to environmental receptors is to assess adverse effects over a gradient of contaminant concentrations. Identifying remediation goals in this manner may require data above and beyond that which is necessary to determine whether existing conditions pose a significant risk. Thus, in the planning stage, it is important to consider whether the risk characterization process should include measures necessary to identify remediation goals.

9.2.5 Feasibility Study Considerations

In the MCP process, the purpose of the Environmental Risk Characterization is to determine whether remediation is necessary. If the assessment results show that a condition of "no significant risk" does not exist, then a Phase III Feasibility Study must be conducted to determine whether cleanup is feasible and to identify the most effective and efficient remediation approach (310 CMR 40.0852). In the feasibility study, technical and economic limitations are considered along with human health and environmental risk characterization results to determine how best to manage the site.

When choosing among remedial alternatives, the risk manager should also consider the environmental risks posed by potential remediation activities. Risks from contaminants in the environment must be balanced with potential harm resulting from habitat destruction during remediation. Guidance on balancing chemical risks against cleanup risks is beyond the scope of this document. Nevertheless, risks associated with each remedial alternative must be taken into account when selecting and implementing remedial action.

[2]The MCP requires remediation to achieve a permanent solution if a significant risk of harm to human health, safety, public welfare *or* the environment is determined.

Wetland habitats are particularly susceptible to damage during remediation. In planning remediation activities in wetland areas, careful attention to adverse impacts on habitat is extremely important. The wetlands regulations forbid "long term" adverse impacts affecting more than 5,000 square feet of inland wetland habitat. If an affected non-rare species will return to the habitat once the project is completed, this is viewed as a "short term" impact. The Massachusetts wetlands regulations (310 CMR 10.00) prohibit *any* adverse effects on *any* amount of vernal pool habitat, or any short or long term adverse impact on the local population of a rare species (since rare species are unlikely to repopulate an area if the local population is eradicated). Project managers should refer to 310 CMR 10.60 to determine whether an impermissible (without a variance) alteration would result from remedial activities in a wetland area.

Other wetland functions, in addition to the provision of important habitats, must be considered in feasibility studies. Examples of such functions are flood control and storm damage prevention. Increased flooding and storm damage could be considered public health and safety risks as well as environmental risks under the MCP, and could require mitigation under the wetland protection act. In any case, these functions must also be considered when choosing among remedial options.

9.3 MCP PROCESS FOR QUANTITATIVE ENVIRONMENTAL RISK CHARACTERIZATION

The MCP establishes a two-tiered process for conducting an Environmental Risk Characterization. Stage I Environmental Screening determines which exposure pathways[3] require further assessment to characterize risk. If the risk of harm from any exposure pathway cannot be ruled out in Stage I, and no "apparent harm" exists, a Stage II Environmental Risk Characterization must be done for that pathway. Stage II Environmental Risk Characterizations employ quantitative methods to evaluate the risk of harm to ecological receptors. Thus, Stage I screening should serve to simplify and streamline many Environmental Risk Characterizations at 21E sites, and to focus resources on the sites where environmental effects are most likely.

[3]An exposure pathway is the link between a contaminant source and a receptor. An example of a relatively simple exposure pathway is direct contact with contaminated soil by terrestrial organisms. An example of a more complex exposure pathway is soil contamination leaching into groundwater and migrating to surface water where aquatic organisms are exposed.

9.3.1 Stage I Environmental Screening

The objective of Stage I Environmental Screening is to identify those exposure pathways which do not require further quantitative assessment and those that do. A pathway can be eliminated from the Stage II quantitative assessment if: (1) significant risk is readily apparent; (2) the exposure pathway is incomplete; or (3) the exposure pathway is complete but the exposure is so minimal that it clearly does not pose a significant risk.

The Stage I Screening should:

1. Identify potential exposure pathways.

2. For each exposure pathway that is complete, *determine whether risk of harm is readily apparent.* If harm is readily apparent, a full quantitative risk characterization may not be necessary.

3. Determine whether each pathway is or could be a complete exposure pathway. *Incomplete exposure pathways* should be eliminated from further consideration.

4. For the remaining complete exposure pathways, *conduct an effects-based screening step to determine whether the pathway clearly does not pose a significant risk.* Eliminate from further assessment any pathways that clearly do not pose a significant risk.

Although each of the tasks listed above should be accomplished in the Stage I Screening conducted at any site, the specific steps and level of detail required will vary substantially for different types of sites and habitats. More detailed Stage I Screening procedures for aquatic, terrestrial and wetland habitats are presented separately in Sections 9.4, 9.5 and 9.6. In general, conducting effects-based screening is simpler for aquatic habitats than for terrestrial habitats, because there are more benchmark values that can be used for screening in aquatic habitats.

The Department anticipates that the Stage I Screening process will eliminate the need for further quantitative assessment at a majority of 21E sites. This guidance document devotes substantially more text to Stage II Environmental Risk Characterization than to Stage I Screening because the Stage II process is much more complex. However, the Stage I Screening Step is expected to be applied at many more sites than the Stage II Environmental Risk Characterization process.

9.3.2 Stage II Environmental Risk Characterization

A Stage II Environmental Risk Characterization is a quantitative, site-specific characterization of the risk of harm to ecological receptors. The appropriate scope and level of detail for a Stage II Characterization will vary widely from site to site. While risk characterization at some sites may be very simple and inexpensive, other sites will require extensive field work and data analysis. For example, some Stage II characterizations may be as simple as performing a more refined effects-based screening using benchmarks more suitable for the specific site than the generic Stage I criteria. Similarly, for some aquatic habitat evaluations, a combination of simple toxicity tests may be sufficient to characterize risk. However, all Stage II Environmental Risk Characterizations, regardless of the habitats involved or the complexity, should follow the basic decision process outlined in this section.

In the *Framework for Ecological Risk Assessment*, EPA breaks the assessment process down into three major components: (1) Problem Formulation, (2) Analysis and (3) Risk Characterization. Within the staged process described in the MCP, these are the basic components of a Stage II Environmental Risk Characterization. Each is described in the sections that follow.

9.3.2.1 Problem Formulation

The first phase in a quantitative Stage II Environmental Risk Characterization is problem formulation. Problem formulation involves the collection and analysis of information needed to determine the appropriate scope and focus of the investigation. **The outcomes of the problem formulation step are the selection of the specific effects (assessment endpoints) that will be quantified in the risk characterization and the identification of the specific measurement endpoints that will best represent those effects.** Problem formulation includes:

1. describing the fate and transport characteristics of the contaminants of concern,

2. identifying exposure pathways and receptors of concern,

3. evaluating the potential toxicological effects of the contaminants on the receptors,

4. using the information cited in (1) through (3) to develop a conceptual model that represents pathways by which contaminants move through the environment to exposure points and through the food web to higher level consumers, and

5. using the conceptual model to select the specific effects on specific organisms that the risk characterization will evaluate.

In some cases, some of the Stage I Environmental Screening activities may serve as preliminary problem formulation steps, but a comprehensive problem formulation should nevertheless be the first step in any Stage II Risk Characterization. Problem formulation provides the justification for the focus of the assessment, and should be fully described in any Scope of Work for a Stage II Environmental Risk Characterization.

During the course of an investigation, a risk assessor may find that information necessary to evaluate the assessment endpoint cannot be obtained. The Department recognizes that the initial problem formulation and conceptual model may require revision or iterative adjustment as the investigation proceeds. The initial problem formulation and conceptual model are, in essence, a Scope of Work. The final problem formulation and conceptual model should be fully described and documented in sections labeled as such in the Environmental Risk Characterization report. The main components of Problem Formulation are described in the sections that follow.

Fate and Transport Characteristics

To meet the requirements of the MCP, both current and foreseeable future conditions must be considered. Current conditions should be characterized in any case. Future conditions must be evaluated if contaminant fate and transport processes are likely to change the nature and distribution of contamination so that future exposures could differ from current exposures. Future conditions are particularly important if contaminant concentrations could increase at any exposure point. When the potential for future migration or bioaccumulation of contaminants exists, the risk assessor should make the most accurate estimate possible of the maximum future contaminant level, and assume that this level will occur under foreseeable future conditions.

Identifying Exposure Pathways and Receptors of Concern

In 310 CMR 40.0904, the MCP states, "*An adequate characterization of the disposal site is a prerequisite to the characterization of the risk of harm to . . . the environment, although the appropriate type and amount of information required to complete a risk characterization will depend on the unique characteristics of a release and/or disposal site*". In the problem formulation phase, both site characteristics and potential ecological receptors should be characterized. Preliminary sampling should be conducted to identify the types of contaminants and the potentially contaminated media present, unless that work has been done in an earlier site investigation phase. A

reconnaissance-level survey should be completed to identify potential exposure pathways and receptors prior to finalizing the sampling plan.

Identifying Potential Toxicological Effects

Once the contaminants of concern and potential receptors have been determined, potential toxicological effects are identified by consulting the scientific literature. Thus, in most cases, **the starting point in an environmental risk characterization is the identification of contaminants present at the site and their known effects.** The cause and effect relationships between the contaminants their potential effects should be built into the assessment in the problem formulation stage, when the risk assessor selects the effects and species on which the assessment will focus. The relationship between the contaminants of concern and the effects to be evaluated should be established in previously conducted controlled scientific experiments as reported in the scientific literature.

Although a preliminary field survey should be conducted during Problem Formulation to identify the exposure pathways and receptors of concern, this initial field survey by itself will not identify the effects to be evaluated. The simple association of contamination with apparent effects observed in a field survey is not necessarily evidence of a cause and effect relationship. Similarly, the absence of apparent effects associated with contamination does not constitute evidence of the absence of risk.

In exceptional cases, when literature information on potential effects is inadequate, an extensive field study conducted during a Stage II Environmental Risk Characterization may be used to establish a cause and effect relationship between contaminants of concern and observed impacts. However, in most cases, published results of previous scientific studies should be used to focus the investigation on effects known to be caused by the contaminants of concern. In general, Stage II field studies should be used only to evaluate the extent and severity of those effects at the site.

Development of the Conceptual Model

The conceptual model is a key component in the design of a site-specific risk characterization. The conceptual model should track the contaminants of concern through environmental transport pathways and through the food web to the organisms that are or could potentially be exposed. It will assist the risk assessor in identifying the receptors that are most susceptible to contamination. The most susceptible receptors are generally the best candidates for indicators of environmental risk at the site. Although other factors must be considered in selecting receptor species, susceptibility should be the primary consideration. In addition to providing a basis for identifying key receptors, the conceptual model will also provide a reference point for

selecting measurement methods that can be used to evaluate the effects of concern.

Identification of Assessment Endpoints

Once the contaminants and exposure pathways of concern at the site have been identified, the scope of the Stage II Environmental Risk Characterization should be narrowed by identifying the specific effects, or assessment endpoints, that will be evaluated. The assessment endpoints are the ultimate focus of the investigation. **For MCP Environmental Risk Characterizations, assessment endpoints are the specific effects that are evaluated quantitatively in the risk characterization.** An assessment endpoint should be described as an *effect* on a *receptor*. Examples of possible assessment endpoints are a change in the structure of a community and the elimination/absence of a species from the affected area as a result of exposure to site-related contaminants.

Although effects and receptors are discussed separately in this section, it is important to remember that these two components are not independent and cannot be considered separately when selecting assessment endpoints. The distribution of contaminants at or from a site determines what organisms could possibly be exposed; the chemical and toxicological nature of the contaminants determines which of those organisms is likely to be affected.

The assessment endpoint or combination of assessment endpoints selected should represent all complete or potentially complete exposure pathways. In the risk characterization process outlined in this document, the selection of assessment endpoints is the crucial step for several reasons:

1. Judgments about the biological significance and regulatory relevance of an environmental effect are exercised in the selection of assessment endpoints; there is no place for such judgments later in the risk characterization process.

2. The selection of assessment endpoints provides the risk assessor with an opportunity to minimize uncertainty about assessment results.

3. The ability of the risk characterization to detect actual effects on biota exposed to contamination depends largely on whether the assessment endpoint is a sensitive indicator of risk; in other words, whether the endpoint species is sufficiently sensitive to the contaminants of concern to detect an effect.

Depending on the nature of the contaminants and the habitat in a contaminated area, site-specific conditions may give rise to a large set of effects that could be considered *potential* assessment endpoints. From all of those possible effects, assessment endpoints are selected by considering appropriate evaluation criteria.

Assessment endpoints should be identified with reference to the conceptual model described previously. The risk assessor should use the conceptual model, along with exposure and toxicity information from studies reported in the literature, to identify the species or communities that are most susceptible and biologically important. The conceptual model, used with toxicity and exposure information from the literature, will serve two purposes in endpoint selection. It will provide the basis for the selection of receptors that will be sensitive indicators of risk. At the same time, it will provide justification for excluding less susceptible and less biologically important receptors from the risk characterization.

Criteria for Selecting Assessment Endpoints

In addition to considering susceptibility and biological relevance in the selection of assessment endpoints, there are other factors that should be considered in endpoint selection as well. Five criteria have been suggested for the evaluation of potential assessment endpoints (Suter 1992):

(1) **unambiguous operational definition**, which provides direction for testing and modeling;
(2) **accessibility to prediction and measurement**, which means that the response of an endpoint can be measured or estimated reliably from measurements of related responses or component responses;
(3) **susceptibility to the hazardous agent**, which results from the potential for exposure and responsiveness to the exposure;
(4) **biological relevance**, which is determined by its importance to a higher level of the biological hierarchy; and
(5) **societal relevance**, which means that the endpoint is valued by the decision maker and the public.

These criteria were developed from the perspective of risk assessors who work on large, complicated sites under federal cleanup programs. DEP believes, however, that they are broadly applicable and provide generally useful guidelines for identifying assessment endpoints for MCP Environmental Risk Characterizations. The criteria and their application to MCP Risk Characterization are described in more detail below.

(1) Unambiguous Operational Definition

An assessment endpoint must have an operational definition. For the purposes of an MCP Environmental Risk Characterization, an assessment endpoint should include a subject (e.g., a specific subpopulation, community or habitat) and an effect on the subject that is measurable (e.g., local extinction or reduction in the subpopulation). Examples of operational definitions are "reduction in a subpopulation" and "absence of a species normally expected to occur." An operational definition allows the assessment endpoint to be related to measurements (Suter 1988).

(2) Accessibility to Prediction and Measurement

Without exception, an assessment endpoint must be either measurable or reliably predictable from measurements. Concepts such as "ecosystem integrity" and "balanced indigenous populations" may be important considerations for risk managers, but they are not suitable endpoints because they cannot be reliably measured or modeled from measurements (Suter 1988). Thus, measurability is a prerequisite for an assessment endpoint.

For effects that are measurable, there are often several measurement methods available. Cost, logistical problems, and measurement uncertainty associated with the available methods may vary. However, these factors should be considered primarily when selecting measurement methods for the chosen assessment endpoints, and should not play a major role in selecting the assessment endpoints themselves.

(3) Susceptibility to the Hazardous Agent

Susceptibility of an organism to a contaminant results from the combination of potential for exposure and the sensitivity of the organism to the contaminants of concern. For most risk characterizations, susceptibility can be determined from the scientific literature on contaminant toxicity and on wildlife exposure factors. There may be exceptional situations, however, where susceptibility itself is evaluated in the risk characterization.

Some potential endpoints are likely to be more susceptible to the contaminants of concern than others. When comparing the utility of potential endpoints, susceptibility should be the primary consideration.

(4) Biological Relevance

In the context of endpoint selection, biological relevance is determined by its importance to a higher level of biological organization. Endpoints selected for MCP Environmental Risk Characterizations should generally be effects on

subpopulations, populations, or communities of organisms. The exceptions are rare and endangered species, in which case the health and survival of an individual organism may be of concern.

The following effects are examples of conditions that are considered biologically relevant for MCP purposes:

- Absence of a species normally expected to occur in the area
- Reduction of a population or a subpopulation
- Change in the structure of a community
- Sublethal effects with potential population level implications, including reproductive effects
- Toxic effects on individual organisms of an endangered, threatened or state-listed species
- Bioaccumulation of a substance to a level that results in toxic effects in the measured species or a species higher in the food web
- Habitat degradation or destruction
- Loss or diminishment of ecological function

These conditions are referred to throughout the rest of the document as indicators of harm. Any of these conditions may be selected as an assessment endpoint for a site-specific risk characterization. Some of these conditions, for example habitat destruction, may be considered evidence of ecologically significant harm. Others, such as sublethal effects, could be considered indicators of the potential for ecologically significant harm. At most sites, a few, but not all, of these conditions are likely to be relevant and applicable to the risk characterization.

The indicators of environmental harm listed above are consistent with the Department's objectives with respect to the level of environmental protection appropriate for MCP investigation and remediation projects. They clearly indicate that assessment objectives should *not* be limited to measurable ecosystem level effects, and that effects at lower levels of biological organization should in many cases be considered significant, even if a quantitative link with ecosystem level effects cannot be established. They also indicate that, except for rare and endangered species, MCP Environmental Risk Characterizations should focus on harm to subpopulations or communities, and not on individual organisms.

The effects on this list should not be used as balancing criteria to compare potential endpoints. For example, sublethal reproductive effects with potential

population impacts are not necessarily less important as assessment endpoints than a reduction or extinction of a local subpopulation. Any condition known to be a potential effect of a contaminant of concern should be evaluated for use as an assessment endpoint.

(5) Relevance to Program Objectives[4]

This criterion addresses whether or not the effects evaluated in the risk characterization are meaningful to risk managers and valued by the Massachusetts Executive Office of Environmental Affairs (EOEA)[5]. In order to be a useful decision tool, **the assessment endpoint must either be valued and meaningful by decision makers or be linked to an effect that is valued.** In other words, the assessment endpoint must be an effect which would warrant a decision to remediate the site, or at least to evaluate the feasibility of cleanup.

When the risk assessor is not certain that a potential endpoint will be meaningful to decision makers, he/she must either (1) identify an alternative endpoint that is a sufficiently sensitive indicator of risk for the same pathway, or (2) explain the link between the assessment endpoint and organisms or functions that are clearly understood and valued. The text that follows provides a general indication of what kinds of organisms and effects are most likely to be meaningful to DEP risk managers, and what kinds of effects are least likely to be valued and understood.

Most Likely to be Valued and Understood

Existing statutes and regulations provide some useful information on public values. While MCP assessment and cleanup projects should not be limited only to those resources already protected by existing laws, those laws do provide valuable information on resources that are clearly understood and valued by regulators and the public in general. The following are examples of resources protected by existing laws:

[4]This criterion has been substantially modified from the "Societal Relevance" criterion proposed by Suter. The reason for the modification is to provide more definite guidance to risk assessors working under the MCP.

[5]"Meaningful and valued" in this context mean that risk managers who are not ecologists and are not familiar with the details of ecological risk assessment are able to make informed environmental risk management decisions based on the information presented in the risk characterization report.

- **Wetlands**, including surface waters, have been recognized by the public at large and the regulatory agencies as important environmental resources, as evidenced by the Massachusetts Wetlands Protection Act and the Federal Clean Water Act.

- **Rare and endangered species** are also highly valued. Since the survival and reproductive success of each individual member may be significant for the survival of the species locally, risk of harm to individual organisms may be significant for these species.

- **Vernal Pools** and their surrounding areas provide breeding and nursery habitats for a number of species, and are recognized as critically important habitat areas. The area within a 150 meter radius of a vernal pool functions as an integral part of the vernal pool habitat.

- **Recreational and commercial resources**, such as shellfish beds and anadromous and catadromous fish runs, are clearly valued by the public and by agencies charged with maintaining and protecting fisheries.

Valued resources are not limited, however, to those already protected by laws other than Chapter 21E. The loss or impairment of *any* natural community[6] attributable to OHM at or from a disposal site could be considered significant at a 21E site. In many cases it is difficult or impossible to detect adverse impacts using community measures. Therefore, an adverse impact on a population or a subpopulation in the vicinity of a site is indicative of a significant risk of harm for MCP purposes.

At most sites, characteristics of subpopulations of **vertebrate species** are considered appropriate endpoint species. An adverse impact on an **invertebrate species which provides a critical food source** for higher organisms is also considered a significant risk of harm. Invertebrate organisms are essential components in food webs. A depletion in an invertebrate population could have an important indirect effect on the predatory species, in that the population of predators could be diminished or depleted by a lack of food. In considering

[6]A community is a complex association of species that are related by food web interactions including the production of and consumption of food, predation and competition for food and shelter.

whether an invertebrate species could serve as an appropriate and meaningful endpoint species, its role in the food web should be a significant factor.[7]

Least Likely to be Valued and Understood

An impact on an individual **population of non-rare invertebrates** is likely to be meaningful to ecologists and risk assessors, but is less likely to be understood by non-specialists. Thus, by itself, an impact on an invertebrate population may not always be a good choice for an assessment endpoint. As a general rule, effects on non-rare invertebrate populations should only be used as assessment endpoints if one of the following is true:

1. The population is a critical component of the prey base, and its function as such would not be replaced by other more tolerant species. (More tolerant means less sensitive to the toxic effects of the OHM at or from the site.) If the depleted population and its function as a prey base is replaced by other organisms of the same ecological guild, there may be no significant risk of harm presented to the environment.

2. The population performs a critical ecological function, such as decomposing organic matter, and that function would not be replaced by other species.

3. The species has been identified as an "indicator species", and the risk assessor has determined that adverse effects on the invertebrate species in question can be used as surrogate measures of adverse effects for other species or the community as a whole.

Again, if an adverse impact on a non-rare invertebrate species is selected as an assessment endpoint, the risk characterization report should clearly explain the link between the endpoint and other valued species or functions.

Adverse effects on **pest and opportunistic** species that populate an area *because* of artificial conditions are another group of organisms that do not make appropriate subjects for MCP Environmental Risk Characterizations. Examples

[7]When an invertebrate species or community is evaluated as an assessment endpoint because of its importance as a prey base, the risk assessment report should clearly describe the function of those invertebrates in the food web. The risk assessment should address the potential for impacts on a particular population to be offset by another less sensitive species within the same guild, which would serve the same function as the depleted species.

include mice, rats and pigeons in populated areas and geese on golf courses. Non-native opportunistic plants include purple loosestrife, phragmites, millefoil and water chestnut.

Toxic effects on pets and livestock should not be used as assessment endpoints in an MCP Environmental Risk Characterization. These organisms are clearly valued, but they are not members of natural communities. Many aspects of Environmental Risk Characterization, particularly the screening steps, do not apply. Therefore, toxic effects on pets and livestock should be evaluated as a risk of harm to public welfare[8]. In those assessments, it may be appropriate to focus on risks to individual organisms, rather than subpopulations. Similarly, risks for people who eat livestock and/or produce should be evaluated as a component of the human health risk assessment, not the environmental risk characterization.

Of the five criteria for selecting assessment endpoints, four are characteristics that *must* be met in order for the endpoint to be useful in the assessment. In order to be selected, an endpoint must: (1) have an operational definition; (2) be accessible to prediction and measurement; (3) be biologically relevant; and (4) be relevant to program objectives. These criteria are of very limited use, however, for comparing the utility and applicability of potential assessment endpoints. It is not the Department's intent to require risk assessors to determine which potential endpoint is more accessible to measurement, more biologically relevant, or more relevant to program objectives than others. Thus, these four criteria should not be used extensively to rank or to compare the utility of potential assessment endpoints, and the final endpoint selection should not rely heavily upon these factors.

Only one criterion, susceptibility to the hazardous material, fully lends itself for use as a point of comparison in selecting among potential assessment endpoints. In general, more susceptible endpoints should be selected in preference over less susceptible endpoints. A decision to select a substantially less sensitive endpoint over one that is more susceptible requires a compelling justification in terms of the other criteria. For example, relative ease of measurement would not justify selection of a significantly less susceptible endpoint.

[8]Risks of harm to health, safety, public welfare and the environment are characterized in separate assessments. Often, safety and public welfare assessments are presented in the health risk characterization report. It may be appropriate, however, to include the public welfare assessment in the environmental risk characterization report if there are common components, for example, if pet and/or livestock exposure estimation procedures are similar to the methods used to estimate wildlife exposures.

Selection of Endpoint Receptors

The first step in selecting the receptor addressed in the assessment endpoints is identifying the groups of organisms that could potentially be affected by contamination at or from the disposal site. In an MCP Environmental Risk Characterization, a receptor may be an organism, group of organisms or a specific habitat affected by oil or hazardous material. Examples of receptors that could serve as endpoint receptors include individual organisms of endangered species, subpopulations, populations, communities and habitats. Potential endpoint species include species of mammals, birds, reptiles and amphibians that are present, or should be present, at or around the site. This topic was introduced earlier in this section, but is discussed below in more detail.

The receptors potentially at risk at or around a given site depend upon:

- the habitat that exists, or would exist in the absence of the site, which in turn determines the organisms that could be supported;
- the distribution of contaminants at or from the site; and
- the susceptibility of the organisms to the contaminants at or from the site, based on published toxicological evidence and exposure information.

Potential endpoint receptors should be identified in conjunction with a habitat evaluation of the site and areas surrounding the site. Habitat evaluation techniques are used to inventory and evaluate environmental resources to determine how well the environmental conditions meet the needs of wildlife. Most of the techniques for evaluating habitats are based on specific species or guilds of species, or on wildlife as a whole. The habitat evaluation procedures assign a level of quality to each area, with assumptions regarding the carrying capacities of the areas. Under the MCP, habitat evaluation techniques should be used as one component of the receptor identification process.

The sensitivity of potential receptors to the contaminants at or from a disposal site is another important consideration in identifying receptors of concern for an assessment. There is wide variation in the sensitivity of different species to different contaminants.

When a species known to be highly sensitive to the contaminants of concern is used as a surrogate for evaluating effects on other species, it is sometimes referred to as an "indicator species". A fairly extensive discussion of the selection and use of indicator species in risk assessments at Superfund sites is presented in a document prepared for EPA by the University of North Carolina entitled *Criteria for Choosing Indicator Species for Ecological Risk Assessments at Superfund Sites* (U.S. EPA 1990).

The potential intensity of exposure is another key consideration in selecting endpoint species. Risk of harm can only exist where there is a potential for exposure. Everything else being equal, risk of harm increases with exposure. EPA's *Wildlife Exposure Factors Handbook* (EPA 1993) provides a wealth of information that can be used for estimating exposure for birds, mammals, reptiles and amphibians. The potential intensity of an organism's exposure to contamination, in combination with its sensitivity, determines the organisms susceptibility.

Effects Considered Indicators of Environmental Harm

The contaminants at any one site may have numerous environmental effects; for cleanup decisions under the MCP, not all of them are relevant. Many effects are not considered adverse, and do not indicate a significant risk of harm to the environment for the purposes of meeting the MCP requirements. Effects that clearly are considered significant were listed as "indicators of harm" in the section on biological relevance. If any of these effects is detected and attributed to OHM at or from a site[9], it poses a significant risk of harm. Thus, any of these effects can be used as assessment endpoints. The indicators of harm are described in more detail in the following sections.

- **Absence of a species**
 For the purposes of an MCP Environmental Risk Characterization, the absence of a vertebrate (and in some cases, invertebrate) species, in an area where its absence is clearly associated with the presence of oil or hazardous material released at or from the site, is considered by DEP to be a significant risk of harm to the environment.
 The level of effort required to evaluate the possible absence of a species depends on a number of species-specific factors, including expected density and mobility. For species that are easily observed (e.g., most birds) with likely exposure pathways to contaminated media, no sightings of the species during at least four reconnaissance-level surveys of the site, conducted during appropriate times of the year, under favorable weather conditions, by trained biologists, is a reasonable basis for concluding the species is absent.

 In cases where the absence of a species is observed during field work but is considered by the risk assessor to have little or no effect on the local natural community, the absence of the species in question may be excluded as an

[9]In order to be considered evidence of significant harm at a site, the condition represented in the assessment endpoint must be clearly associated with the contamination of concern.

assessment endpoint if the risk assessor can make a compelling argument against biological significance.

- **Reduction of a Population or Subpopulation**
 A population is defined as a group of organisms of the same species, generally occupying a contiguous area, and capable of interbreeding. In this guidance, the term subpopulation refers to the portion of a population known or likely to be exposed to contaminants at or from the disposal site of concern.

 Not all population reductions constitute environmental harm. The potential impacts of a population reduction should be evaluated with respect to the ecological function of the population in question. In determining whether a potential population reduction is an appropriate assessment endpoint, the risk assessor should consider whether the species in question is an important prey item or provides habitat structure.

 An assessment endpoint that addresses a population reduction should also specify the magnitude of change that would be considered significant. Thus, when the risk assessor determines that site conditions could potentially reduce an ecologically important population, the assessor must also state the magnitude of the change (percent reduction) that will be evaluated, and justify that decision. For example "a reduction in game fish of 10% or more" is a complete assessment endpoint statement (provided the choice of the value 10% is justified).

 Reduction of a population may be measured either directly by field studies or indirectly by controlled laboratory or field toxicity tests that focus on organism-level effects. Field studies can provide direct evidence of population reduction in a contaminated area, but they cannot always pinpoint the cause of those effects.

 Populations and subpopulations are subject to natural temporal and spatial variability. It may be difficult to distinguish a contaminant-related reduction from a natural fluctuation, especially in a field study that is focused on a small subpopulation. Therefore, it may be most meaningful to compare the size or density of the potentially affected population or subpopulation to normal ranges, as reported in the literature. When a field study, rather than a range reported in literature, is used to evaluate a potential population reduction, **a statistically significant reduction in a population or subpopulation relative to that found in a reference area should be considered evidence of harm.**

Toxicity tests can provide information that complements the results of field studies, enhancing the utility of both for evaluating potential population reductions. When relevant test methods are available, the use of controlled toxicity tests to evaluate the effects of oil or hazardous material avoids the problem of distinguishing contaminant-related effects from natural variations. However, the extrapolation of organism-level effects to population-level effects introduces additional uncertainty into the assessment.

- **Change in the Structure of a Community**
 For MCP purposes, changes in community structure attributed to contaminants at or from a site may be considered indicators of harm to the environment. Examples of community structure changes include alterations in the relative abundance of various species, or changes in the number and kinds of species that can survive in a particular habitat (USEPA 1989). Evaluation of community structure should, where appropriate, include consideration of vegetation as well as wildlife.

 When deciding whether a particular change in community structure should be selected as an assessment endpoint, the potential biological significance of the change should be considered. A decrease in the population of a keystone or important prey species, relative to other populations, should be considered significant risk of harm. Not all shifts in community structure, however, are indicative of harm. For example, a shift toward lower proportions of one species in a benthic community may not be harmful if its function in the community and the food web were replaced by another species. The burden of demonstrating that an observed change is insignificant rests with the risk assessor.

 The diversity and richness of an existing community determine the feasibility of measuring this endpoint at a site. For example, in aquatic habitats, structural changes in benthic communities, which contain large populations of many species are generally easier to detect than community-level changes in the water column.

- **Bioconcentration/Bioaccumulation**
 Bioconcentration in aquatic organisms and bioaccumulation in others provides direct evidence of exposure. However, bioaccumulation (or bioconcentration) may not by itself be indicative of toxic effects. A decision to consider bioaccumulation as an indication of harm, rather than just evidence of exposure, should be based on the toxicity of the chemical in question and the likely fate of the chemical in the food web. Bioaccumulation in itself should be considered evidence of harm if:

1. A toxic body burden is detected or predicted in the species in which the accumulation is measured,

2. Organisms higher up the food chain could ingest toxic doses or could accumulate the contaminant over time to the point of attaining a toxic body burden.

The selection of test species for assessing bioaccumulation should take into account the sizes of the species' home ranges relative to the contaminated area. Bioaccumulation may be difficult to detect in a species whose home range is large relative to the site. Furthermore, if a substance is detected in an organism with a relatively large home range, the proportion of body burden attributable to uptake at the site may be difficult to determine. Therefore, it is important to choose test species whose home range corresponds as closely as possible with the size and location of the contaminated area.

- **Habitat Degradation or Destruction**
 This condition may be defined as the reduction of the area of a habitat or the reduction or elimination of structural vegetative components or critical features typically found within a habitat type. Critical features for a habitat type include:

 · soils;

 · hydrologic regime including water quality, turbidity, depth, and velocity;

 · vegetative community, in terms of its

 - Composition (types of plant species)

 - Structure (amount and percentage of vegetative "layers" such as herbaceous, shrubs and various sized and shaped trees); and

 · vertebrate and invertebrate sources of food within the food web.

 When the elimination or reduction of a critical plant species or food source is clearly associated with the presence of contamination at or from the site, it should be considered evidence of harm to the environment for purposes of the MCP. Examples of **habitat degradation** include: (1) loss of plant life at a site or in a section of a water body affected by the release and (2) reduction of a food source. Thus, the observation of stressed vegetation is evidence of habitat degradation, if the stress is due to contamination at the site. Another indication

of habitat degradation is the proliferation of opportunistic species, which may occur in conjunction with a reduction of critical plant species[10].

Readily apparent physical or chemical alterations in soil, sediment or surface water may also constitute evidence of habitat destruction or degradation. Examples of **habitat destruction** include saturation or coating of large areas of surface water, sediment, banks or shoreline with oil or hazardous materials; contaminant concentrations in surface water high enough to elicit avoidance of an area where a fish would normally pass through or go to feed or spawn; algal blooms from nutrient loading to a water body, which in turn reduces dissolved oxygen levels; the death of trees and/or shrubs at a site in a woodland area; and the presence of VOCs in soil vapor high enough to elicit avoidance of an area or cause lethal effects in burrowing animals.

Habitat loss or degradation is a species-dependent endpoint. The species of concern, and their habitat requirements, should be considered in determining whether conditions such as those described in the previous paragraph indicate actual habitat degradation or loss, and thus harm to the environment. The ecological value of specific habitat features depends on the requirements of the species that are present or expected to be present in the absence of the contamination.

For terrestrial habitats, some of the habitat features that are vital to a species or group of species can be identified by working backward through a habitat assessment method to identify the predictors that lead to a high rating. A number of habitat-based evaluations have been developed (Atkinson 1985). A list of references related to terrestrial habitat evaluation is included at the end of Section 9.5.

At sites where habitat degradation is visible or easily measured, and other endpoints are difficult or impractical to measure, habitat degradation by itself would be an appropriate endpoint, and would provide support for a decision that remediation is necessary. The use of habitat degradation as an assessment endpoint may eliminate the need for more resource-intensive quantitative evaluation. However, absence of visible habitat degradation by itself does not demonstrate a condition of "no significant risk of harm", and, therefore, may

[10]The composition of the vegetative community is determined by many physical and chemical factors other than the presence of contamination. If a field survey is used to assess the loss of plant life, the selection of an appropriate reference area is critical.

not be a useful and appropriate assessment endpoint for sites where degradation is not readily apparent.

For example, consider a wetland where the population of an important plant species has been reduced or eliminated. It may be difficult to determine whether such a reduction actually represents a degradation of the habitat. Nevertheless, the population reduction in and of itself may represent a significant risk of harm to the environment. In such a case, the reduction of the plant population would be an appropriate endpoint. Evidence of habitat reduction or degradation is not necessary to determine whether a significant risk of environmental harm exists.

Habitat destruction resulting from physical disturbances during remedial activities must be evaluated when the feasibility of remediation is evaluated. The mechanisms of disturbances from remedial activities differ from the chemical effects of contamination. Even when physical degradation or destruction of habitat is not evaluated in the baseline risk characterization, it must be considered when evaluating and selecting remedial technologies.

- **Loss or Diminishment of Ecological Function**
 In this guidance, the term "ecological function" refers to services provided by groups of organisms or an ecosystem relative to the flow of energy and matter through an ecosystem. When contaminants change the species composition and relative abundance of populations in a community, the patterns of matter and energy flow within the ecosystem may also change. For example, one of the ecological functions of wetlands is to "remove or transform excess nutrients, organic compounds, trace metals, sediment and refractory chemicals from water as it moves downstream (Preston and Bedford 1988). Reduction or elimination of key species may interrupt the flow of energy and nutrients to other species not directly experiencing a toxic effect (U.S.EPA 1989a).

 The functions most likely to be observed or measured at a site are the production of food from solar energy and the recycling of minerals and nutrients by decomposition. If plant life is adversely affected by a contaminant, the ecosystem as a whole may capture less solar energy and thus support less animal life. If microbial or invertebrate populations are disrupted, decomposition of dead plants and animals may not occur rapidly enough to supply sufficient mineral nutrients to sustain the plant community (U.S.EPA 1989a).

 Loss of ecological function is likely to be a useful and appropriate assessment endpoint for only a limited number of sites. In many cases, a quantitative

evaluation of loss of ecological function would require long-term resource-intensive studies. Nevertheless, it is included here as an indicator of harm and a potential assessment endpoint for two reasons. The first is to affirm that, when a loss of ecological function is observed and is attributable to the release of oil or hazardous material in question, DEP considers such a loss to be evidence of biologically significant harm, and thus indicative of a significant risk of harm to the environment. The second is to provide the option to use loss of ecological function as an endpoint in cases where it would be a sensitive indicator of risk and would be easily evaluated relative to other potential assessment endpoints.

As a rule, the risk assessor would *not* be expected to provide justification for not selecting loss of ecological function as an endpoint, if such a loss is not evident from the available site information. Like habitat destruction and degradation, diminishment of function is not expected to be a sensitive indicator of harm in most cases. It also may be less accessible to measurement than other potential assessment endpoints. Since loss of ecological function is likely to be a good endpoint choice in relatively few cases, risk assessors are not expected to routinely justify decisions against selecting such loss as an assessment endpoint.

It should be recognized that not all of the listed conditions are equal in importance; some are only significant under certain circumstances. For some of the listed conditions, the significance and suitability as an assessment endpoint depends on the receptors exposed and their ecological niche or function.

A risk characterization for a specific site may contain any number and any combination of assessment endpoints. The combination of endpoints selected must represent all exposure pathways of concern, so that cleanup decisions based on the characterization results will remedy all existing and potentially significant risks of harm.

In determining whether contamination at a specific site has caused or could cause harm, the characterization of adverse effects should focus on the groups of organisms actually exposed to oil and/or hazardous materials at or from the site. Observation of a regional population impact is not necessarily a requisite for a finding of ecologically significant harm. For example, the death of half of the birds of a species that feed at a 10 acre site in Worcester would be a clear reduction in the subpopulation that is exposed at the site. Although those deaths may not represent a discernible reduction in the population of that species in the state, or even in Worcester, DEP would consider this condition to be "environmental harm", because the subpopulation exposed at or near the site has clearly been adversely affected.

The focus on exposed subpopulations should not, however, mean that the assessment of impacts should be limited to the area of the site. Contaminant transport through the food chain to receptors that spend most or all of their time at some distance from the site should be considered when substances known to bioaccumulate are present.

Justification for Not Evaluating a Potential Effect

Justification for not evaluating a potential effect should reflect and be consistent with the guidance and criteria for selecting assessment endpoints. Strong reasons for selecting certain effects on specific receptors as sensitive indicators of harm provide the best rationale for not evaluating the other potential effects in the quantitative risk assessment. For example, a demonstration that Endpoint A is more susceptible to the contamination at the site than Endpoint B provides a strong justification for focusing on Endpoint A in the assessment.

Identification of Measurement Endpoints

A measurement endpoint is a measurable response to a contaminant that is related to the assessment endpoint (Suter 1993). In some cases, assessment endpoints can be evaluated directly, and there is no distinction between the measurement and assessment endpoint. An example is the use of a field study to directly measure a population reduction. Often, however, direct measurement is not feasible, and indirect measurement must be employed. The result of an indirect method is referred to as a measurement endpoint, and is used to approximate the assessment endpoint.

An example of an assessment endpoint that may be estimated rather than measured directly is a change in the reproductive capacity of a mink population. To evaluate the potential for such a change to occur as a result of exposure to site contaminants at or from the site, the results of reproductive toxicity studies published in the scientific literature combined with site exposure estimates could be used as a measurement endpoint. Other examples of measurement endpoints are the results of field toxicity tests and the comparison of site concentrations with published benchmark values.

The relationships between measurement endpoints and assessment endpoints enable the risk assessor to use the results of field observations, bioassays and literature reviews to decide whether a significant risk of harm has resulted or is likely to result from the contaminants of concern. Using a measurement endpoint to approximate or estimate an assessment endpoint introduces additional uncertainty into the assessment. The stronger the relationship between the assessment and measurement endpoints, the lower the uncertainty. Thus, to a certain extent, the risk assessor can minimize the uncertainty about an assessment by selecting assessment endpoints for which closely related measurement methods are available.

The conceptual model should reflect the links between the measurement and assessment endpoints. The strength of these links may control a large share of the uncertainty about the assessment results. Selection of measurement endpoints that are clearly and strongly linked to the assessment endpoint will minimize uncertainty about the overall conclusion of the risk characterization.

One way of addressing the uncertainty about the accuracy of individual measurement endpoints is to conduct several different measurements to evaluate each assessment endpoint. Multiple lines of evidence will strengthen the support for the conclusions, and will enable the risk assessor to consider a weight of evidence when drawing conclusions from the results of measurements made at a site. In considering the results of each measurement and the uncertainty associated with it, the risk assessor must exercise and justify a judgment about the assessment endpoint itself[11]. If a "weight of evidence" shows no harmful effect, the investigator may conclude that a condition of "no significant risk of harm to the environment" exists.

To evaluate a specific assessment endpoint, a number of measurement endpoints may be used. Any particular measurement technique may have strengths and weaknesses that must be considered in planning the assessment and analyzing data. The major measurement approaches are defined below for the purposes of this document. Most of the following text is taken from EPA guidance (EPA 1988 and EPA Region I 1989):

- **Chemical Analyses**
 Chemical analyses of environmental media are routinely performed at most sites to determine the nature, extent and distribution of contamination. If done concurrently with toxicity testing and field studies, chemical analysis is also crucial in identifying a relationship between contaminants and effects at sites.

 When planning sampling programs and analyzing the results, it is important to consider potential limitations of the information provided by the data. One common problem in using chemical data in ecological risk assessment is that the detection limit for a given chemical may be greater than concentrations of environmental concern. Therefore, a laboratory result of "non-detect" does not

[11]The "weight of evidence" approach applies separately to individual pathways and assessment endpoints. If evaluation of any one assessment endpoint results in a finding of significant risk, the conclusion of the risk characterization is that significant risk exists. "Weight of evidence" does not mean that significant risk associated with one endpoint can be balanced or moderated by findings of no significant risk for other assessment endpoints.

necessarily mean that the contaminant is present below a toxic level (EPA Region I, 1989).

In general, non-detect results provide an adequate and defensible basis for not including a chemical as a substance of concern. However, in limited circumstances, a substance that is present in environmental media at levels below the detection limit may be of concern in a Stage II Risk Characterization. At present, only certain surface water contaminants are known to be of potential concern at levels below detection limits. The reasons that very low environmental concentrations could pose a significant risk of harm are:

(1) Some substances may bioaccumulate to levels of concern in plant or animal tissue even when the concentrations in the environmental media (soil or groundwater for example) are below detection limits. When substances known to have been released at the site, and Stage I Screening indicates the need for a Stage II characterization, chemical analysis of biota for those substances may provide a more sensitive measure of exposure than chemical analysis of the environmental media.

(2) Some substances may exhibit toxicity even when present at levels below the detection limit. If the risk characterization includes conducting toxicity tests on environmental media from the site, then the potential for non-detected substances (both site-related and non site-related) to contribute to the toxicity must be taken into account when interpreting the results of the tests.

These cautions notwithstanding, the Department usually considers non-detect results as sufficient justification for a decision to exclude a substance from further consideration in the risk characterization.

Conventional parameters and methodologies may not be sufficient to adequately evaluate the nature and toxicity of site related contaminants. Many metals and inorganics can occur in different chemical states, (for example, chromium III and chromium VI) or as organometallic complexes (for example, tributyl tin and methyl mercury). The toxicities of different chemical forms of a metal may vary widely, so simple elemental analysis may not be sufficient to characterize the risk posed by the contamination. The project manager and risk assessor should consider the history and nature of the site when identifying the necessary analyses.

- **Benchmark Comparisons**
 Chemical concentrations detected in environmental media or in the tissues of exposed organisms may also be compared with published criteria to assess the severity of the contamination. These comparisons are referred to in this document as the benchmark approach. An example is the comparison of surface water concentrations to USEPA Ambient Water Quality Criteria (AWQC) (USEPA 1986 as amended). When relevant values are available, benchmark comparisons can be valuable as components of the suite of measurements used to determine a weight of evidence. In order to obtain analytical data that are comparable to appropriate benchmarks, the basis of potentially useful benchmark values should be taken into account when the sampling plan is developed.

- **Toxicity Quotient Method**
 In this guidance document, toxicity quotient method refers to the comparison of the dose received at the site with a Lowest Observed Adverse Effect Level (LOAEL) or a No Observed Adverse Effect Level (NOAEL) dose reported in the literature. These comparisons are a subset of benchmark comparisons, but they are discussed separately because they are applied in different situations. Benchmark comparisons involve direct comparisons of tissue or environmental media concentrations with concentrations reported in the scientific literature to be associated with effects, while the toxicity quotient method requires estimation of a dose that an organism would receive from exposure to a given contaminant concentration in and the environmental medium.

- **Field Studies**
 Field surveys fall into two general categories, which are useful at different assessment stages: (1) preliminary surveys, which are usually qualitative in nature, and are done for screening and planning purposes and (2) quantitative field studies, which are used to measure and evaluate environmental effects. A preliminary qualitative field survey should be conducted, almost without exception, for all Stage II Characterizations during the Problem Formulation phase, to identify exposure pathways and potential receptors. A quantitative survey may be conducted during the Analysis phase along with other measurement approaches to evaluate an assessment endpoint. This section focuses on quantitative field studies.

 Field studies provide information on the presence, abundance, diversity and richness of species and communities at a site. Information on age structure and reproductive success can also be obtained from field studies. Field studies

provide *direct* information on actual toxic effects occurring at the site. In order to correlate field study results with chemical contamination, samples for chemical analysis must be collected from locations representative of the conditions in the field study area.

The following excerpt from *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document* (Warren-Hicks, et al.) makes a compelling case for the value of field studies as components in quantitative assessments:

> There are several distinct reasons for implementing field studies as assessment tools at hazardous waste sites. First, indigenous organisms serve as continuous monitors of environmental quality by integrating potentially wide fluctuations in contaminant exposure. Second, an accurate field assessment of natural populations directly measures adverse effects; thus, extrapolations from laboratory data are not necessary for interspecies sensitivity, environmental variation, pulsed dosing, chemical interaction, or bioavailability. Third, results of the assessment of indigenous populations are directly interpretable, since effects are quantified for the resources actually at risk. Fourth, the results of assessments of effects on indigenous populations are easily understood by managers, regulators and the general public.

The results of a field study are analyzed by comparing the observations in the area affected by the contamination (i.e., population census results or community metrics) to the same measurements from a reference area that has not been affected by the contamination, or to measurements reported in the scientific literature. The identification of a suitable reference area is critical for a field study. If the reference area is not comparable to the affected area, or is affected by different stressors, the assessment results are likely to be misleading. The availability of appropriate reference areas often limits the applicability of field studies in quantitative assessments.

Another limitation on the use of field studies is the potential presence of confounding stressors. Some of the parameters measured in field studies are affected by numerous conditions in addition to the presence of contamination, including physical stressors and natural variability. A field study will provide a reliable and sensitive measure of risk only if (1) the parameters evaluated are more sensitive to the contamination of concern than to other stressors, and (2) if natural variations neither mask nor exaggerate the effect of the contamination.

- **Toxicity Tests**
 Toxicity tests measure the effects of contaminated media from the site on the survival, growth and/or reproduction of aquatic and terrestrial organisms (EPA 1988). Often, samples of soil, sediment or water are collected from the site and tested in a laboratory with stock (i.e., nonresident) organisms, such as sheepshead minnows, fathead minnows, daphnia and earthworms. Alternatively, toxicity testing may also be conducted with resident species in a mobile laboratory or in situ[12].

 These tests are particularly useful in assessing the toxicity of compounds that are present at the site but are not detected in standard chemical analyses. Furthermore, toxicity tests can provide a direct estimate of the toxicity of the mixture present at a specific site, whereas at present there are no accurate methods for predicting the interactive effects of chemicals in mixtures. Conversely, when a toxicity test does not link adverse effects with exposure to specific chemicals, it may be difficult to develop cleanup criteria, or attribute the adverse effects to a particular source (U.S.EPA, Region I 1989). Limitations of toxicity tests, particularly those performed in a laboratory on stock organisms include: genotypes that are not representative of the diversity found in nature; species that may not be prevalent in or relevant to the ecosystem of concern; limitations on the behavior of organisms that act as compensatory mechanisms in the natural environment; and the need for extrapolation from the organism-level to population-level and community-level effects.

- **Biomarkers**
 Biomarkers are measurements of conditions in individual organisms that serve as sensitive indicators of exposure to contaminants and/or sublethal stress (EPA

[12]The operating definitions of the terms "toxicity test", "bioassessment techniques", and bioassays vary among writers and risk assessors. To reduce confusion, it may help to recognize here some of the different definitions in use. One source states that bioassays are laboratory-based tests that incorporate rigorous experimental protocols and controls, and include both toxicity tests and bioaccumulation studies. The same source defines "bioassessment" techniques as field-based analyses that lack strict experimental controls (Burton 1992). Some investigators use the term "bioassay" to denote the types of tests referred to in this document as "toxicity tests" (EPA Region I 1989).

In this document, the term toxicity test refers to all field and laboratory tests that involve the measurement of biological effects associated with the controlled exposure of organisms to site-related oil or hazardous material. In field-based toxicity tests, indigenous or standard test organism may be exposed to environmental media (soil, surface water or sediment) at known contaminant levels. In laboratory toxicity tests, stock organisms are exposed to known concentrations of a chemical.

1988). Usually biomarkers are physiological or biochemical responses such as changes in enzyme concentration, genetic abnormalities and histopathological abnormalities[13].

Biomarkers have been used fairly extensively as indicators of exposure of fish to environmental toxins. Examples of biomarkers that have been used most frequently include:

DNA abducts:

Segments of DNA that have chemicals (contaminants) bound to them are known as DNA abducts. The most sensitive method currently available to detect a wide range of compounds bound to DNA is ^{32}P-postlabeling.

Cytochrome P4501a levels:

Elevated levels of cytochrome P4501a are observed as a response to exposure to aromatic hydrocarbons.

Selection of Measurement Methods and Endpoints

The strength of the link between a measurement endpoint (measurement result) and the assessment endpoint should be considered at two points in the risk characterization process. First, in the problem formulation step, when selecting the measurement methods that will be used to evaluate the assessment endpoint, those that will produce results more strongly linked to the assessment endpoint should be given preference. Second, in the risk characterization step, when deciding how much weight to give to each measurement result, more weight should be given to the measurement endpoints with stronger links to the assessment endpoint. In either case, the important attributes of the measurement method/endpoint to be considered are similar.

The attributes of a measurement endpoint that determine the strength of the link with the assessment endpoint fall into three broad categories: (1) attributes related to the strength of association between the measurement and assessment endpoint; (2) attributes related to data quality; and (3) attributes related to study design and execution. Following are brief definitions and descriptions of the important measurement endpoint attributes (in italics) and the categories under which they fall.

[13]Some sources also consider measures of bioaccumulation as biomarkers, but, in this document, the term is used only for measurable biochemical changes. The simple accumulation of contaminants in plant or animal tissue is referred to as bioaccumulation.

(1) **Strength of Association**

Strength of association refers to the applicability of the measurement endpoint to the assessment endpoint and the correlation between the results of the measurement and the level of risk or the severity of the effect. To evaluate the strength of association, the risk assessor should consider the following attributes of the measurement endpoint:

Biological relationship between the measurement and assessment endpoint refers to the correlation/applicability of the measurement endpoint with respect to the assessment endpoint. Biological relationship pertains to similarity of effect, target organ, mechanism of action and level of ecological organization.

The biological relationship is strongest when a field study is used to measure the assessment endpoint directly, and therefore the measurement and assessment endpoints are equivalent.

For measurement methods and endpoints, such as toxicity tests and benchmarks, that evaluate the assessment endpoint indirectly, the risk assessor should consider whether the chemical, physical and biological processes link the measurement endpoint with the assessment endpoint directly or indirectly. More specifically, the risk assessor should determine whether:

- the level of ecological organization is the same for both endpoints, and
- the target organ and mechanism of action evaluated are the same.

Correlation of stressor to response relates to the ability of the endpoint to demonstrate effects from exposure to the stressor, and the ability to correlate the magnitude of the effect(s) with the degree of exposure. To evaluate the correlation of the stressor to the response, the risk assessor should consider the number of studies of good quality that show a causal or correlative relationship between the endpoints. The risk assessor should also consider whether a statistical correlation has been demonstrated.

Sensitivity of the measurement endpoint for detecting changes in the assessment endpoint means the ability of the measurement endpoint to detect changes in the assessment endpoint caused by the stressor. Sensitivity of the measurement endpoint depends in part on its susceptibility to the same stressor(s) as the assessment endpoint. To evaluate the

sensitivity, the risk assessor should consider the ability of the measurement endpoint to distinguish stressor effects from natural variability, and should evaluate the percentage of total possible degree of variability that the endpoint is able to detect. If an inferential statistical test is applied, the power of that test to detect a given change should be evaluated.

Utility of the measure for judging environmental harm is the ability to judge results of the study against well-accepted standards, criteria, or objective measures. Examples of objective standards or measures for judgment might include ambient water quality criteria, sediment quality criteria, biological indices, and toxicity or exposure thresholds recognized by the scientific or regulatory community as measures of environmental harm.

(2) **Data Quality**

Extent to which data quality objectives are met refers to the degree to which data quality objectives are designated that are comprehensive and rigorous, as well as the extent to which they are met. To evaluate this attribute, the risk assessor should consider the appropriateness of data collection and analysis practices. If any data quality objectives are not met, the reason for not meeting them and the potential impact on the overall characterization should be clearly documented.

(3) **Study Design and Execution**

Study design and execution refers to the overall quality of the study. The attributes in this category describe the ability of the study, or measurement, to detect effects of concern and to discern the effects of contaminants from effects due to confounding factors.

Site specificity refers to the representativeness of data, media, species, environmental conditions and habitat types that are used in the measurement endpoint relative to those present at the site. To evaluate site specificity, the risk assessor should consider the extent to which each of these factors are derived from or reflect the site.

Site specificity is strongest when the assessment endpoint is measured directly by a field study.

When a toxicity test is the measurement endpoint, the degree to which the spatial and temporal exposure patterns at the site are represented by the exposure patterns in the toxicity test is an important consideration. If exposure patterns at the site differ substantially from the exposures evaluated in the toxicity test, the site specificity of the measurement endpoint will be low.

For field studies, including sample collection for chemical analyses, ***temporal and spatial representativeness*** are important factors in evaluating the appropriateness of the study design. Spatial representativeness refers to the extent to which the study area and the locations of measurements overlap the area impacted by the stressor. Temporal representativeness means the overlap between the measurement period and the period during which the effects would be likely to occur (daily, weekly, seasonally and annually).

Use of a standard method refers to the extent to which the study follows specific protocols recommended by a recognized scientific authority for conducting the method correctly. Examples of standard methods are study designs or chemical measures published in the Federal Register or the Code of Federal Regulations, developed by ASTM, or repeatedly published in the peer-reviewed literature. If a standard method must be modified to be applicable, or if an unpublished method is used, the measurement method and endpoint may introduce uncertainty.

Sensitivity of the measurement relates to the ability to detect a response in the measurement endpoint. The sensitivity of the measurement endpoint reflects its ability to discriminate between responses to a stressor and those resulting from natural or design variability and uncertainty.

Quantitativeness relates to the degree to which numbers can be used to describe the magnitude of the response of the measurement endpoint to the stressor, as well as whether the results are objective or subjective.

Again, each attribute is important both in selecting the measurement endpoints during problem formulation and later in evaluating the weight of evidence in the risk characterization phase. However, some of the attributes may be evaluated differently in the problem formulation step than in the risk characterization step. For example, during problem formulation, the quality of data associated with a

measurement endpoint may be judged to be relatively high based on the potential performance of the measurement techniques. Nevertheless, the actual performance of the measurements may fall short of those expectations. If so, the quality of data may be judged to be relatively low for the same endpoint when the weight of evidence is evaluated during risk characterization. The application of these attributes in evaluating the weight of evidence to characterize risk is discussed further in Section 9.3.2.3.

9.3.2.2 Analysis

In the **Analysis** step, the measurement endpoints are evaluated. The analysis step involves collection and integration of information on contaminant toxicity, contaminant concentrations and spatial distribution, and exposure conditions (temporal and spatial patterns), as well as observation or prediction of adverse effects, as appropriate for the methods selected.

Data necessary to characterize environmental risk often differ from those collected to assess public health risk. The toxicity of various contaminants and exposure patterns for non-human receptors differ from those applied in human health risk assessment, and these differences should be considered in the sampling plan. The appropriate investigation approach is highly dependent on the receptors of concern. Therefore, sampling and analysis considerations are discussed separately in this document for aquatic, terrestrial and wetland habitats.

One consideration that applies to environmental risk characterization at all sites is the importance of preparing an assessment plan ***before*** conducting field studies or collecting samples for chemical analysis or toxicity testing. Such a plan will facilitate the co-location of chemical samples with toxicity tests and field studies. Co-location of analyses is necessary to enable investigators to correlate chemical concentrations in environmental media with tissue concentrations and biological effects in plants and invertebrates, because physical, chemical and biological conditions often vary widely over small areas. Ideally each sample collected for a toxicity test should be split for chemical and physical analyses. Physical characteristics, such as soil or sediment grain size, salinity, and organic carbon content can be critical in differentiating stressor-related effects from natural variability associated with physical differences at sampling locations.

9.3.2.3 Risk Characterization

In the risk characterization step, the measurement results are evaluated to determine whether they support a conclusion of no significant risk for each assessment endpoint. When more than one measurement has been conducted to evaluate an assessment endpoint,

and the results of those measurements do not agree, those results are considered in combination, and a conclusion is based on a "weight of evidence".

The "weight of evidence" approach should be applied separately to individual assessment endpoints. An indication of "no significant risk of harm" for one endpoint should not be used to temper results that indicate a significant risk of harm for a different endpoint. For example, the absence of a change in community structure should not be balanced against evidence of a population reduction within that community.

Furthermore, **in considering the weight of evidence for an assessment endpoint, "evidence of harm" and "indication of potential for harm" should be considered separately**. Section 9.2.1 described four criteria that must be met in order to conclude that a condition of no significant risk to the environment exists. Two of those are evaluated in the environmental risk characterization: (1) no evidence of biologically significant harm and (2) no indication of the potential for biologically significant harm. If either of these is not met, the risk assessor cannot conclude that a condition of "no significant risk of harm" exists. Thus, even without evidence of harm, a significant risk of harm may exist, in which case the feasibility of remediation must be evaluated. Nevertheless, the distinction between risk of harm and evidence of harm may be an important balancing factor in evaluating the feasibility of remediation.

Risk of harm and evidence of harm may be evaluated using different measurement endpoints. Evidence of harm can be obtained from field studies that directly measure population parameters and community metrics. Readily apparent stressed biota are also considered evidence of harm. Many of the measurement methods used to evaluate assessment endpoints indicate "potential for ecological harm", but do not provide "evidence of harm". Benchmark comparisons, laboratory toxicity tests, and the toxicity quotient method are examples.

The results of direct measures of harm are often considered along with other measurements to evaluate the "weight of evidence" of *risk* of harm. Direct measures should not necessarily be given a higher weight than indirect estimates or extrapolations. In other words, field study results that do not provide evidence of harm should not necessarily outweigh the results of other measurements and extrapolations. When the results of different measurements diverge, the relative weight given to each should be based upon the weight given to each measurement endpoint and upon the strength of the result, as described in the text that follows.

Considerations when Determining the Weight of Evidence

In evaluating the weight of evidence for an assessment endpoint, the risk assessor must consider, in combination, (1) the weight given to the measurement endpoint, (2) the result of the measurement and (3) the strength of the result. Each of these considerations is described in more detail below.

(1) The relative weight of the measurement endpoint should be determined. The weight of the measurement endpoint is an indication of how well it represents the assessment endpoint. The following factors are considered in weighting each measurement endpoint:

(a) strength of association with the assessment endpoint;

(b) study design; and

(c) data quality.

These factors and the attributes that define them are described in Section 9.3.2.1. The risk assessor must determine separate weights for each of the three factors above, and then combine them to determine the overall weight. The overall weight for each measurement endpoint should be expressed in terms of "high", "medium" or "low".

At present, to determine the overall weight for each assessment endpoint, DEP recommends considering strength of association, study design and data quality separately, and assigning a qualitative weight of "high", "medium" or "low" to each factor. At present, DEP recommends the qualitative approach, as outlined in these steps:

(1) first, each attribute associated with each of the three factors above should be assigned a weight of "high", "medium" or "low" for the measurement endpoint in question.

(2) The weights of the individual attributes should be considered in combination to determine a weight of "high", "medium" or "low" for strength of association, data quality and study design and execution.

(3) To determine the overall weight for a measurement endpoint, equal consideration should be given to strength of association and study design.

Data quality should be considered as a pass/fail factor. If data quality is inadequate, the measurement endpoint should not be considered at all. If data quality is adequate, the measurement endpoint is considered in the weight of evidence evaluation, but data quality itself is not given further consideration.

(2) The result of each measurement refers to whether the measurement indicates a risk of harm to the environment. There are three possible results for any measurement:

(a) Positive indication of risk;

(b) Negative, or no indication of risk;

(c) Indeterminate.

(3) The strength of the result (i.e., strong or weak) refers to how clear or definite a positive or negative result is. In other words, the risk assessor should consider whether results that indicate risk are strong or weak, and whether results that do not indicate risk are strong or weak.

Integrating Measurement Information to Determine the Weight of Evidence

The risk assessor must use professional judgment to integrate the information outlined above to determine whether the overall evidence indicates a significant risk of harm or not. At this point in time, DEP suggests a qualitative approach.

Table 9.1 uses an example to show how the results of a qualitative weight of evidence evaluation could be portrayed. For this example, assume that three measurement endpoints, referenced as A, B and C, have been used to evaluate an assessment endpoint. Further assume the following:

- Measurement endpoint A was given a high weight and produced a strong positive indication of risk
- Measurement endpoint B was given a high weight and produced a strong negative result
- Measurement endpoint C was given a low weight and produced a weak negative result

Table 9.1

MEASUREMENT RESULT	HIGH WEIGHT	MEDIUM WEIGHT	LOW WEIGHT
Yes - Strong	A		
Yes - Weak			
Indeterminate			
No - Weak			C
No - Strong	B		

In this example, the results of measurements A and B contradict each other. Measurement C does not serve to sway the conclusion since it was given a low weight and produced a weak result (this would also be true if it had produced a weak yes rather than a weak no). However, the question of whether the results of A and B together indicate risk or not require the risk assessor to consider (1) the relative weights (the same in this case); (2) the attributes considered in the weighting process; and, perhaps most importantly, (3) whether endpoints A and B are functionally related, so that the negative result of B modifies the positive result.

To further explain the meaning of the term "functional relationship" used in (3) above, suppose that Endpoint A involves comparing site concentrations with concentrations reported in the literature to be associated with toxic effects. Suppose also that endpoint B provided a measure of bioavailability, and that it shows low bioavailability for the contaminant of concern. It may be reasonable to conclude that, taken together the results of A and B do not indicate risk. On the other hand, if B were a different measure of toxicity (from A), it may be appropriate to conclude that A indicates a significant risk of harm, and that B does not argue against that conclusion.

The guidance in this section describes a procedure for evaluating the "weight of evidence", in which the strengths and weaknesses of different lines of evidence are considered in a systematic and objective manner. It also provides an outline for describing and documenting assessment decisions in risk characterization reports submitted to DEP for review. The application of this procedure will not, however, always lead to an unequivocal conclusion. As in the example above, the conclusion drawn from a weight of evidence evaluation may, in the end, require substantial professional judgment. Nevertheless, the application and documentation of this procedure will make the evaluation process more transparent. The bases of the risk

assessor's judgment will be more evident to those reviewing the risk characterization report, and to the risk managers who must base remediation decisions upon it.

In MCP Environmental Risk Characterizations, selection of assessment endpoints is critically important because of their role in the risk assessment/risk management process. When a quantitative risk characterization detects a risk of harm for an assessment endpoint, the conclusion must be that a significant risk of harm to the environment exists, and that remediation must be considered. The biological significance of a potential effect and its relevance to policy goals should be considered when selecting assessment the endpoint(s). Only endpoints that potentially represent a significant effect should be selected for an MCP Environmental Risk Characterization.

After the endpoints have been selected, the risk characterization step should not be influenced by judgments about the biological significance of the assessment endpoint, or about the relevance to DEP policy goals. If the analysis activities indicate a risk, the conclusion of the MCP Environmental Risk Characterization must be that significant risk of harm to the environment exists. That conclusion cannot then be tempered by an argument that the endpoint is not really significant with respect to policy goals.

The Risk Characterization section of the report should describe the sources and magnitude of the uncertainty associated with each measurement endpoint and with the overall conclusions. The most significant sources of uncertainty should be identified, and the relative significance of each should be discussed in the risk characterization section of the report. When a weight of evidence approach is used, much of the information needed for the uncertainty characterization will be developed in the process of selecting measurement methods and characterizing risks.

9.3.2.4 Risk Management

Risk management decisions are separate from the risk characterization process. This section on risk management is included in the guidance for completeness, to place the risk characterization requirements in context. Under the MCP, risk management decisions address questions such as:

- Is remediation technically and economically feasible?
- What is the most appropriate technology for cleanup and/or exposure mitigation?
- How quickly must remediation be done to protect public health and the environment?

The purpose of risk characterization under the MCP is to provide an objective basis for risk management decisions. If the environmental risk characterization concludes that a

condition of "no significant risk of harm" to the environment does *not* exist, or has not yet been achieved, then that risk must be eliminated in order to achieve a Permanent Solution. A Permanent Solution (i.e., a Class A RAO) must be attained if feasible. Determining the feasibility of attaining a Permanent Solution requires identification and evaluation of remedial action alternatives (which may include a no-action alternative). For comparing alternatives, eight evaluation criteria are set forth (310 CMR 40.0858):

(1) The comparative effectiveness of the alternatives;
(2) The comparative short-term and long-term reliability of the alternatives;
(3) The comparative difficulty in implementing each alternative;
(4) The comparative costs of the alternatives;
(5) The comparative risks of the alternatives;
(6) The comparative benefits of the alternatives;
(7) The comparative timeliness of the alternatives; and
(8) The relative effect of the alternatives upon non-pecuniary interests.

When comparing alternatives and evaluating the feasibility of a permanent solution, both the nature and magnitude of the risk(s) may be considered.

At the risk management stage, however, consideration of the nature and magnitude of the risk is relevant only to the question of whether a permanent solution is currently feasible. It does not apply to the question of whether significant risk exists and remediation is necessary to achieve a permanent solution. If the risk characterization concludes that a condition of no significant risk has not yet been achieved, then remediation is necessary to achieve a permanent solution, and that conclusion cannot be modified through the risk management process.

9.3.3 Concluding Remarks

The intent of this guidance is to encourage the design of risk assessments that are consistent with the program objectives, which are reflected in the general criteria discussed in Section 9.3.2.1 of this document, and to promote risk management decisions that are consistent from site to site. The process outlined in Section 9.3 should be followed for every Stage II Environmental Risk Characterization, and should be fully documented in each risk characterization report. It provides a framework for decisions about the scope and focus of an environmental risk characterization, as well as for the interpretation and application of the results. The selection of assessment and measurement endpoints can only be justified within the context of this process.

Although each risk characterization must include all of the components outlined above, the level of effort and detail appropriate for assessments at various sites is expected to vary

widely. The habitat types and organisms that exist, or should exist, at a specific site are a major factor in designing the risk characterization. The available bioassays, field investigation techniques and published criteria differ between aquatic, terrestrial and wetland habitats. In Sections 9.4, 9.5 and 9.6 of this guidance, Stage I Screening and Stage II Environmental Risk Characterization are discussed separately for aquatic, terrestrial and wetland habitats.

9.4 AQUATIC HABITATS AND ORGANISMS

Oil and/or hazardous materials (OHM) at or from sites can migrate to surface water or sediment by groundwater transport, surface runoff or direct discharge. Where OHM are present in sediment[14] or surface water, or could potentially reach surface water or sediment, exposure of aquatic and benthic organisms is likely. Furthermore, any terrestrial fauna using the water body and bank area as a source of food and water and/or as a primary habitat will also be exposed. Amphibians, reptiles, birds and mammals can be exposed to water and sediment contaminants at the perimeter and on the banks of water bodies, as well as in floodplain areas. Stage II Environmental Risk Characterizations conducted to assess surface water and/or sediment contamination must address exposure of terrestrial and wetland wildlife, as well as aquatic organisms, to surface water and sediment contaminants.

The need for a quantitative site-specific risk assessment depends in part upon whether the site-related contaminant levels are elevated relative to the concentrations prevalent in the vicinity of the site. Before the Stage I Environmental Screening step, concentrations detected in surface water and sediment at the site should be compared with background levels. Background conditions are defined in Section 9.4.1. Subsequently, as an initial Stage I Screening step, surface and sediment concentrations may be compared to contaminant levels that represent "local conditions". If concentrations at the site are consistent with background and/or local conditions, it may be possible to eliminate the need for further assessment. Local conditions are concentrations of OHM that are higher than background levels, but nevertheless ubiquitous throughout the vicinity of the site and are attributable to sources other than the site in question (see Section 9.4.2).

Figure 9.2 shows a decision flow diagram for assessing and managing risks from sites in aquatic environments. The procedure presented in the diagram and the test that follows begins with the assumption that oil and/or hazardous material (OHM) has been detected in the surface water and/or sediment, or that OHM is likely to reach the surface water or sediment in the future. The decision process should be applied to surface water and sediment separately. As shown in the Figure, comparisons of detected concentrations with background conditions, local conditions and other screening criteria all play a part in defining the focus and scope of Stage II quantitative risk characterization in aquatic habitats.

[14] Sediments means all detrital and inorganic or organic matter situated on the bottom of lakes, ponds, streams, rivers, the ocean or other surface water bodies. Sediments are found: (a) in tidal waters below the mean high water line as defined in 310 CMR 10.23; and (b) below the upper boundary of a bank, as defined in 310 CMR 10.54(2), which abuts and confines a water body.

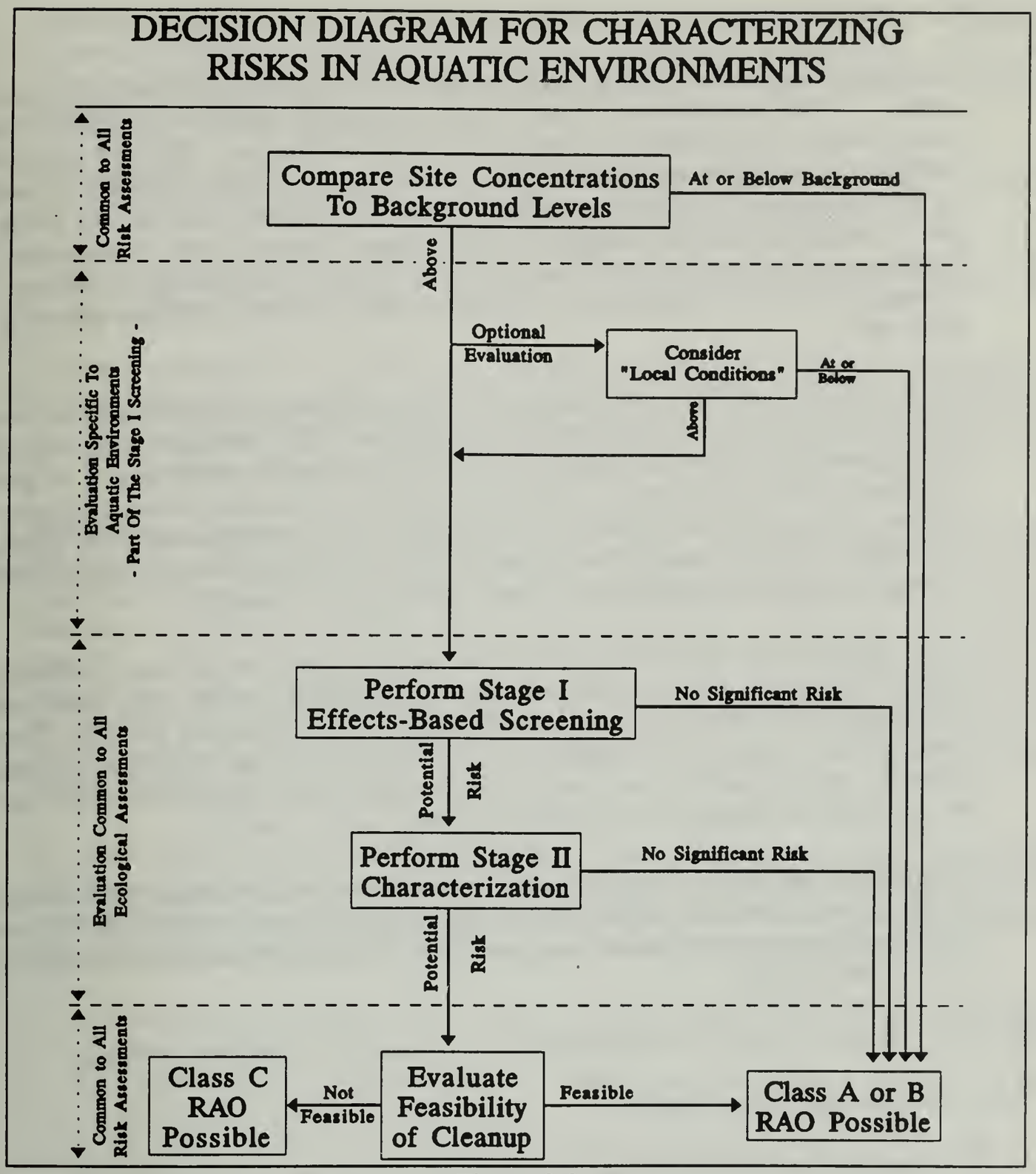

DECISION DIAGRAM FOR CHARACTERIZING RISKS IN AQUATIC ENVIRONMENTS
Common to All Risk Assessments
Compare Site Concentrations To Background Levels
At or Below Background
Above
Evaluation Specific To Aquatic Environments - Part Of The Stage I Screening -
Optional Evaluation
Consider "Local Conditions"
At or Below
Above
Evaluation Common to All Ecological Assessments
Perform Stage I Effects-Based Screening
No Significant Risk
Potential
Risk
Perform Stage II Characterization
No Significant Risk
Potential
Risk
Common to All Risk Assessments
Class C RAO Possible
Not Feasible
Evaluate Feasibility of Cleanup
Feasible
Class A or B RAO Possible

Figure 9.2

A narrative description of the decision process outlined in Figure 9.2 follows:

1. Concentrations detected in the surface water and/or sediment are compared to background levels. If the concentration of any OHM detected at the site is consistent with background conditions, those substances are not assessed further. The MCP states that background concentrations constitute a condition of no significant risk of harm to health or the environment (310 CMR 40.0902(3)). If concentrations at the site are elevated above background then the assessment should proceed to the next step. (Comparison to background is not required at this point; it may be done at any point in the process. It is suggested as a first step because DEP believes that is the most efficient approach in most cases.)

2. As an optional initial Stage I Screening step, concentrations detected in the surface water and/or sediment may be compared to "local conditions". This may allow many sites out of the system before the effects-based Stage I Environmental Screening step (i.e., prior to comparing site concentrations to screening criteria). If site-related concentrations are elevated relative to local conditions, then the assessment should proceed to the effects-based Stage I Environmental Screening step. If the concentration of any detected OHM is consistent with local conditions, no further assessment is required.

3. If any OHM is found to be elevated in comparison to background and local conditions, a Stage I Environmental effects-based screening is required. In this step, site-related concentrations are compared with screening criteria specified in Section 9.4.2.2. If each concentration in surface water and/or sediment is lower than the applicable screening criterion, the risk assessor may conclude that no significant exposure pathways exist, and no further assessment or remediation of surface water is required.

4. If any site-related OHM is present in surface water and/or sediment above the screening criteria (as well as above background levels and local conditions), then the risk of harm from exposure to the contaminated water and/or sediment must be evaluated in a Stage II Risk Characterization.

Background and local conditions are discussed in more detail in the sections that follow.

9.4.1 Background Determination

In determining the extent of contamination, and in identifying the contaminants of concern, the key question is whether the levels of each site-related hazardous material exceed background concentrations of that substance. In all risk characterizations conducted to meet the requirements of the MCP, the detected levels of OHM should be evaluated to determine whether they are consistent with background conditions. **If the presence of a substance in sediment and surface water is consistent with and is attributable to background**

conditions, that substance should not be included in the quantitative risk assessment. Section 2.3 of this Guidance Document discusses "background" issues in detail. This section addresses issues specific to surface water. Again, background conditions should be evaluated separately for sediment and surface water.

In Section 40.0006, the MCP defines background as those levels of oil an hazardous material that would exist in the absence of the disposal site of concern which are:

(a) ubiquitous and consistently present in the environment in the vicinity of the disposal site of concern; and

(b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, releases to groundwater from a public water supply system, and/or petroleum residues that are incidental to the normal operation of motor vehicles.

Background sediment or surface water samples should be collected from an appropriate reference area, which is an uncontaminated area otherwise comparable to the site. For sites impacting streams and rivers, stations either on tributaries or upstream of the point of discharge are usually appropriate for collecting background sediment or surface water samples. For lakes and ponds, reference stations in the same water body may be appropriate. However, this option requires careful consideration, since contamination may be naturally distributed throughout the water body over time. As an alternative, reference stations may be located on a nearby lake or pond where physical, chemical and biological conditions are known to be similar.

For small ponds or streams, background samples may be taken from a nearby water body with similar physical, chemical, biological and geologic characteristics. To evaluate whether a potential reference pond is suitable, the investigator should consider a number of historical, chemical and physical factors, including whether the proposed reference pond is:

- susceptible to non-point source runoff that differs from runoff affecting the surface water at the site,
- a location where biological control substances, such as sodium arsenate or copper sulfate, have been used in the past,
- the same general morphology and hydrology as the pond being assessed, and
- similar in terms of size, depth, trophic status and geochemical conditions.

Comparisons of site concentrations to background concentrations should be made on a chemical-specific basis. A chemical may be considered **attributable to background** conditions and may be eliminated from the quantitative risk assessment if:

(1) the detected concentrations are consistent with background concentrations determined specifically for the site in question, and

(2) the spatial distribution of concentrations at the site does not indicate that the chemical was "released" at the site.

The Office of Watershed Management is currently identifying "least contaminated conditions" for surface water in different eco-regions in Massachusetts. DEP expects the data obtained through that project to be helpful in the future in identifying background concentrations for individual sites.

9.4.2 Stage I Screening

Stage I Screening involves two steps: (1) exposure pathway identification and (2) effects-based screening. In the first of these, all potential receptor groups are identified and the viability of each potential exposure pathway is evaluated. An exposure pathway is the link between the contaminant source and any group of organisms that could come into contact with the contamination. Any potential exposure pathways that are incomplete, and are not likely to be complete in the foreseeable future, should be eliminated from further consideration.

Exposure pathways may also be eliminated from the quantitative risk assessment if harm is readily apparent and the risk assessor can conclude, without performing a quantitative risk assessment, that a condition of "no significant risk" does *not* exist. For aquatic habitats, the Stage I screening steps are described in more detail below.

9.4.2.1 Local Conditions

Contaminants from sources such as other disposal sites, permitted discharges and many non-point sources do not conform to the MCP definition of background. To clearly distinguish these contaminants from background, the concentrations resulting from such releases are referred to as *local conditions*. Local conditions are levels of OHM present consistently and uniformly throughout the surface water body, or throughout a larger section of a river that contains the area potentially affected by contamination at or from the site. This situation is common in Massachusetts where many industrial facilities were historically built along the banks of rivers. Hot spots and localized contamination are not considered local conditions. Technically, the comparison of site conditions to local conditions is parallel to comparisons of site contaminants to background levels. Physically similar nearby sections of a river should be used as reference areas. Like background, local conditions must be assessed on a chemical specific basis, and must be evaluated separately for sediment and surface water. When concentrations of a substance are consistent with local conditions, further assessment

of the risk posed by that substance in that medium may is not required. The following paragraphs elaborate on the reasons for this provision.

If concentrations of oil and/or hazardous material in surface water or sediment are elevated above background levels, exposure of aquatic organisms is certain to occur, given the ubiquitous presence of organisms in aquatic environments. The question of whether a *site-related* exposure pathway exists, however, depends upon whether the OHM in the surface water and/or sediment is from the site. If concentrations of an OHM are consistent with local conditions, exposure to contaminants *from the site* may not be discernible, and thus the incremental risks may not be quantifiable.

Furthermore, if site concentrations are comparable to levels consistently found throughout the surface water or sediment, it may not be feasible to remediate the sediment or surface water in the immediate vicinity of the site. For example, if sediment concentrations at a site on a river exceed background levels, but are consistent with local conditions, sediment cleanup may not be possible. In a dynamic aquatic environment, removal of contamination from a limited area may not result in a permanent concentration reduction if the area is likely to be re-contaminated by sediments from upstream areas.

9.4.2.2 Identification of Complete Exposure Pathways

In surface water and/or sediment, the mere presence of contaminants is generally sufficient to demonstrate the presence of a complete exposure pathway for aquatic organisms. If surface water organisms are present in the affected area, or would be present in the absence of site-related contamination, then it is reasonable to assume that they will be exposed to any surface water contamination present in that area. Thus, in most cases, to determine whether a complete exposure pathway exists, the risk assessor has only to determine whether aquatic organisms are or should be present; it is *not* necessary to identify which species inhabit the surface water in question. Similarly, if any benthic organisms exist or could potentially exist in the areas where sediment is contaminated, it is reasonable to assume that those organisms will experience exposure to those contaminants. Thus, the detection of elevated levels of contamination in sediment or surface water, or the potential for elevated levels to occur in the future, constitutes identification of a complete exposure pathway.

Examples of potential exposure pathways in aquatic habitats include:

- Exposure of aquatic (including benthic) and terrestrial organisms to *sediment* contaminated by:

 (a) contaminated groundwater discharging to surface water
 (b) erosion of contaminated surface soil
 (c) runoff of contaminated surface water

(d) seep or discharge of oil or other hazardous materials

- Exposure of aquatic or terrestrial organisms to *surface water* contaminated by:

(a) contaminated groundwater discharging to surface water
(b) erosion of contaminated surface soil
(c) runoff of contaminated surface water
(d) seep or discharge of oil or other hazardous materials
(e) re-suspension of contaminated sediments

As an example of exposure pathway screening, consider a situation where groundwater contamination exists in the vicinity of a surface water body. If it can be demonstrated that the contamination will not reach the surface water body or the underlying sediment, exposure of aquatic organisms to groundwater contaminants can be ruled out in Stage I because the pathway is incomplete.

For any complete exposure pathway, an effects-based screening step should be conducted.

9.4.2.3 Effects-Based Screening

In this step, each complete exposure pathway is evaluated to determine whether the exposures are likely to be significant[15]. If significant exposures are determined to be unlikely for any pathway, that pathway can be eliminated from further consideration in the risk assessment.

Screening in aquatic habitats is facilitated by the availability of numerical criteria that can be used to determine the potential for significant effects in surface water and/or sediment. When used for screening, these criteria are presumed to be protective for all potentially exposed organisms. Thus, the need to identify and describe exposure pathways for specific types of organisms in Stage I is eliminated.

The effects-based screening step involves using appropriate benchmark concentrations (for sediment and surface water) to determine whether each complete exposure pathway warrants a comprehensive quantitative risk evaluation. Toxicity-based benchmark values that may be used to determine the need for further quantitative risk evaluation are discussed below:

[15]In this context, exposures are significant if they could potentially result in a significant risk of harm to the environment. An insignificant exposure is one so small that the potential for harm can quickly and easily be ruled out. For example, simple comparisons to benchmark concentrations may enable the risk assessor to determine that an exposure is insignificant.

Potential Effects from Sediment Exposures:

The need to quantify risks from sediment exposures can generally be ruled out if the sediment concentrations of all contaminants of concern are lower than the "Effects Range-Low" (ER-L) for that substance. ER-Ls are levels identified in *The Potential for Biological Effects of Sediment-Sorbed Contaminants Tested in the National Status and Trends Program* (NOAA 1991). A revised derivation of the ER-Ls is published in EPA's *Sediment Classification Methods Compendium* (EPA 1992b), which cites *Development of an Integrated Approach to the Assessment of Sediment Quality in Florida* (MacDonald 1992). This approach is further discussed in *Incidence of Adverse Biological Effects within Ranges of Chemical Concentrations in Marine and Estuarine Sediments* (Long, et.al. 1995).

NOAA considers the ER-Ls appropriate guidelines for screening, and has used them for that purpose. Although the ER-Ls are not "no effects" levels, measurable effects at lower concentrations are considered unlikely. The ER-Ls are based on studies in which paired data on chemical concentrations and biological effects were obtained for sediment samples from numerous locations around the country. The values represent the 10th percentile of the concentrations at which effects were observed. Since many of the data are from sites with multiple contaminants, the observed effects in some cases may be caused by other chemicals in the mixture, and cannot necessarily be attributed to the substance of concern. At the lower concentrations associated with effects (i.e. below the 10th percentile), the probability that the observed effects were caused by the substance in question is relatively low. Therefore, the ER-Ls are considered sufficiently protective. As is the case with any benchmark comparison, the analytical techniques used to obtain site data should be similar to those used to derive the benchmark concentrations, so that the values will be comparable.

The revised effects range values are based on studies conducted in marine and/or estuarine systems, and may be less accurate for freshwater habitats. Sediment Quality Guidelines established by the Ontario Ministry of the Environment may be used for evaluating freshwater sediment concentrations. As NOAA or other agencies publish screening values based on freshwater studies, those data may be incorporated into the effects-based screening step for freshwater systems.

Sediment Quality Criteria published by EPA may also be used as screening criteria. To date, EPA has published values for fluoranthene, phenanthrene, acenaphthene, dieldrin and endrin. These values are only considered valid, however, within a certain range of sediment organic carbon content, and should never be applied above that level.

Potential Effects from Surface Water Exposures:

The need to quantify effects from surface water exposures can be ruled out if the surface water concentrations of all contaminants of concern are lower than the Ambient Water Quality Criteria (AWQC) published by EPA in *Quality Criteria for Water* (EPA 1986 and updates), and are not likely to exceed these values in the future. The chronic value for the appropriate medium (marine or fresh water) should be used whenever available.

Unfortunately, criteria are available for only a few substances, primarily inorganic substances. Screening values for substances without established Criteria will be developed at a later date. In the interim, DEP considers the chronic "lowest observed effect levels" (LOELs) acceptable for screening purposes. EPA's Quality Criteria for Water (1989 with updates), contains chronic LOELS for freshwater and marine organisms for numerous compounds. In the absence of published values, an ecological risk assessor may consult the literature to identify an appropriate LOEL.

If the risk of harm cannot be ruled out for an exposure pathway, an evaluation of that pathway by a Stage II Risk Characterization is necessary. As an example of effects-based screening, consider a situation where contaminated groundwater is discharging or is expected to discharge to surface water. If the concentrations in the surface water are lower than the screening criteria presented in this section, and are not likely to exceed them in the future, then the risk assessor can conclude that the exposure pathway is not significant, and the groundwater-sediment-surface water exposure pathway need not be evaluated quantitatively in the Stage II Risk Characterization. However, if surface water concentrations are, or could potentially become, higher than the screening criteria, risks from the pathway must be evaluated quantitatively by a Stage II Environmental Risk Characterization.

Screening criteria are proposed for the purpose of ruling out pathways, not individual chemicals. If a pathway is not ruled out, risks from all chemicals that result in exposure by that pathway should be evaluated in Stage II, even if some of those substances are present at levels below their screening criteria.

9.4.3 Stage II Environmental Risk Characterization (Aquatic Habitats)

This section focuses on chemical sampling and analysis considerations and assessment methods available for measuring effects and estimating risk at sites where oil or hazardous material has been released to surface water and/or sediment. General guidance on the entire Stage II Risk Characterization process was presented in Section 3.0, and will not be repeated here. The measurement methods and issues discussed in this section are relevant to the

identification of measurement endpoints in the problem formulation phase of a Stage II Risk Characterization.

9.4.3.1 Sampling and Analytical Considerations

The toxicity and availability of surface water and/or sediment contaminants at a specific location depend on a variety of physical and chemical water parameters. Characteristics of surface water and sediment that may influence toxicity and exposure include:

- pH, alkalinity, salinity, ammonia, phosphorous, nutrients, baseline metals, dissolved oxygen and temperature.
- Hardness, which may affect the toxicity of many chemicals, and is required to calculate ambient water quality criteria for some metals.
- Particle size distribution for sediments, which is used for determining the benthic organisms likely to be present and for identifying depositional areas.
- Organic carbon content, which determines the extent to which hydrophobic toxic organic compounds sorb to the organic component of sediments. This parameter is required for the application of sediment quality criteria for organic chemicals, and for using predictive models of toxicity and bioaccumulation.
- Silt and clay content of sediment, which is related to the natural metal content of sediments, and should be considered when evaluating whether metals concentrations are elevated.
- Acid volatile sulfides (AVS), which affect the bioavailability of some metals in sediments. The acid volatile sulfides/simultaneously extracted metals ratio (AVS/SEM ratio) is useful in evaluating the bioavailability of inorganic substances in sediments. This approach is relatively new and is still being evaluated by EPA, but it does provide one means for evaluating potential metal bioavailability.

Surface water and sediment sampling plans should be developed in consultation with an ecological risk assessor to ensure the collection of the necessary data for interpretation of analytical results and assessment of risks. Significant spatial and temporal variation in chemical and biological conditions are likely to occur in most surface water bodies. Sampling locations should be uniformly distributed throughout the area of concern, and sampling density should be sufficient to obtain representative data. Samples for chemical and physical analyses and for toxicity tests should be collected from the same locations at the same time.

To obtain chemical data that accurately represents exposures of benthic organisms to sediment contaminants, sampling depth is critical. The vertical distribution of sediment contamination is an important consideration for assessment and remediation decisions. Many organisms are more likely to be exposed to contaminants near the surface of the sediment than to contaminants at depth. Furthermore, concentrations of sediment

contaminants are often stratified, rather than distributed evenly with depth. Thus, sampling procedures should be designed to differentiate contaminant concentrations at various sediment depths. Detritus should not be removed when collecting sediment samples. If the depth distribution of contaminants at a site has already been established, samples may be collected from the specific depths of concern. If the depth distribution has not been characterized, sediment core samples should be collected and sectioned for analysis.

9.4.3.2 Quantitative Ecological Risk Assessment (Aquatic Habitats)

As described in Section 9.3, the Stage II Environmental Risk Characterization begins with the *Problem Formulation Phase*, which identifies the assessment endpoints and selects the measurements that will be used to evaluate them. The risk assessor should identify a combination of measurement and assessment endpoints that will support a conclusion regarding the risk of ecological harm.

The measurements are conducted in the *Analysis Phase*. In the *Risk Characterization Phase*, the results of the measurements are considered in combination to determine whether the weight of evidence indicates a significant risk of harm for the assessment endpoint. Measurement methods commonly applied in aquatic habitats are described in the following section.

Measurement Methods/Measurement Endpoints (Aquatic Habitats)

A number of investigatory approaches are available for evaluating ecological effects in aquatic habitats and organisms from exposure to hazardous materials. Examples of approaches applied in aquatic habitat assessments include:

- Field studies
- Toxicity tests
- Benchmark approach
- Toxicity quotient method
- Tissue residue analysis
- Biomarkers

Assessment approaches and specific tests should be selected based on their relevance to the assessment endpoints of concern. Each approach has strengths and weaknesses. More than one measurement approach should be used to evaluate each assessment endpoint in order to obtain multiple lines of evidence to apply a weight of evidence approach in the risk characterization. Following are brief discussions of the advantages and disadvantages of each approach listed above:

Field Studies

As outlined in Section 9.3, two types of field surveys are routinely employed in ecological risk assessments: (1) qualitative surveys to identify potential receptors and exposure pathways and (2) quantitative field studies, which may be used as one of several measurement methods to evaluate an assessment endpoint in Stage II Risk Characterizations. This section focuses on the latter type.

In assessments of impacts on aquatic organisms, field studies are used to obtain measures of population and community structure for plankton, periphyton, macroinvertebrates and fish. Typical measures of community structure include relative abundance, species richness, and indices of community organization (LaPoint and Fairchild 1988). For most 21E sites, however, the affected area is too small to result in a change in fish community structure; therefore these measurements are limited to smaller less mobile organisms.

The presence or absence of indicator species is also used to assess adverse effects to ecological communities (LaPoint and Fairchild 1988). This approach can be successfully applied to limited types of contaminants. For example, the total number of insects in the orders Ephemoptera, Plecoptera and Trichoptera are referred to as the number of "EPTs". These orders are sensitive to metals and inorganics, and provide an index of effect for those substances.

For a more detailed discussion of these and other measurement approaches, the reader is referred to *Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference Document* (Warren-Hicks, et al., 1988).

Natural spatial and temporal variations as well as the impacts of non-site related stressors complicate the use of field studies. To an extent, the effect of these variations on the study result can be minimized by the selection of appropriate reference areas. The EPA's Rapid Bioassessment Protocols are a good source of information on correctly selecting reference areas for aquatic field assessments. However, the availability and identification of suitable reference areas is also a potential limitation in field studies. As a result, the design of field studies and interpretation of the results for quantitative assessment purposes requires extensive knowledge and experience.

Toxicity Tests

Toxicity tests were defined and described in the General Considerations section of this guidance. Numerous standardized and widely applied toxicity tests are available for evaluating toxicity to aquatic organisms. Toxicity tests offer a direct method for assessing the toxicity of specific contaminants, and are often a key component of aquatic assessments.

Toxicity tests may be conducted by exposing organisms either to environmental media from the site or to media spiked in the laboratory with a single chemical or a mixture of chemicals. One disadvantage of toxicity tests conducted with environmental media containing chemical mixtures is that the toxic effects of individual chemicals cannot be determined. This is a particularly important limitation for aquatic assessments in areas affected by other sources. A disadvantage of laboratory toxicity tests is the inability to accurately simulate complex natural aquatic systems. Furthermore, in tests conducted on stock organisms in the laboratory, genotypes are not representative of the diversity found in nature, the species tested may not be prevalent in or relevant to the ecosystem of concern, and test conditions limit the behaviors of organisms that act as compensatory mechanisms in the environment. Nevertheless, standardized tests are widely available and offer the advantage of providing direct information on toxic effects. Toxicity tests are particularly useful as components of risk assessments for aquatic habitats.

For full descriptions of established methods, the reader is referred to EPA and ASTM guidelines (ASTM 1990, EPA 1989b, and EPA 1991). In order to correlate toxic effects with chemical contamination, split samples should be used for chemical analysis and bioassay samples.

Benchmark Approach

This approach involves comparing water, sediment or tissue concentrations with levels of concern identified in the literature. In addition to their use in toxicity-based screening as described in the previous section, benchmark comparisons can also be used as a component of the quantitative risk characterizations at some sites. This approach is generally considered more useful for small simple sites and for large sites with one dominant contaminant. There is a substantial amount of available toxicity information from which benchmark values for toxic effects in aquatic habitats can be derived. However, because the quality of published toxicity studies and the interpretation of these studies may be inconsistent, careful evaluation of the original studies is necessary in most cases. Examples of potentially useful values are EPA Ambient Water Quality Criteria and EPA sediment quality criteria.

One advantage of this approach is that it does not require the identification of a reference area or reference conditions for comparison purposes. A major disadvantage is the fact that site specific physical and chemical conditions are generally not accounted for, and these factors can significantly affect the availability and toxicity of a contaminant.

Toxicity Quotient Method

In the toxicity quotient method, risks are characterized by calculating the ratio of the dose from site exposure to a "no observed adverse effect level" (NOAEL) dose or a "lowest observed adverse effect level" (LOAEL) dose obtained from scientific literature[16]. Often, site related doses are estimated rather than measured. These exposure estimates introduce an additional degree of uncertainty. Given that uncertainty, as well as limitations in the execution of studies based on literature and the availability of data and methods needed for other approaches to aquatic habitat assessments, the quotient method is not widely used to assess risks to aquatic organisms.

Tissue Residue Analysis

Residue analysis involves analyzing the appropriate plant or animal tissues to determine whether the contaminants of concern have accumulated in the organism. Residue analysis can confirm the accuracy of exposure and uptake estimates. In some cases, residue analysis can be paired with literature data to assess the potential for toxic effects. Depending on the toxicity of the chemical in question and its potential to move up a food web, bioaccumulation to a toxic level may be an assessment endpoint and may be considered evidence of harm to the environment.

For substances known to bioaccumulate (some inorganic substances and semi-volatile organic compounds, including PCBs) residue analysis is almost always useful as a reality check on exposure assumptions. This measure of exposure may then be combined with available data on the toxic effects, in order to assess the potential for ecological risk associated with that degree of bioaccumulation or exposure. For substances that do not have a strong tendency to bioaccumulate (such as volatile organic compounds), residue analysis is rarely warranted.

[16]In this document, the term toxicity quotient method does not include comparisons of contaminant concentrations in environmental media to published standards or benchmark concentrations, for example, EPA Ambient Water Quality Criteria. Such comparisons are referred to as "benchmark comparisons", or the "benchmark approach".

Chemical-Specific Considerations (Aquatic Habits)

The most effective approach to environmental risk characterization depends in part on the type of contamination present at the site. When selecting measurement methods, the risk assessor should consider the fate of the substance in the environment, the potential for bioaccumulation or bioconcentration and the known effects of the substance. Following is a brief discussion of some of the chemical-specific considerations for a few of the contaminants commonly encountered in surface water and sediment at disposal sites. This is not a comprehensive list of considerations, and the substances addressed represent a small fraction of all contaminants of concern at sites. Nevertheless, this brief discussion does provide an indication of the importance of considering chemical characteristics when planning an assessment.

Mercury

Mercury is highly toxic in sediment and surface water at low concentrations and also accumulates to higher concentrations in higher trophic level organisms. Detection limits for mercury are often an issue since very low levels can bioconcentrate to harmful levels at higher trophic levels. Because the availability of mercury is dependent on a number of physical and biological factors, a combination of investigatory approaches is needed to evaluate risk from mercury.

Sediment toxicity testing and analyzing the tissue residues of higher trophic levels is recommended. In situ bioaccumulation studies with caged bivalves may be a useful way of determining potential availability of inorganic and methylmercury in specific areas and under different conditions. In situ methods are preferred to laboratory bioaccumulation tests because of the importance of methylation to the availability of mercury and the likelihood that laboratory conditions would not be representative of field conditions (e.g., methylation of mercury in the water column may be of major importance in some systems). Seasonal changes in methylation rates should be considered in experimental design. In summary, for assessing the potential ecological impacts of mercury, the most useful assessment methods are toxicity testing, benthic macroinvertebrate community assessments and determination of bioavailability and bioaccumulation.

PAHs

PAH contaminated sediments can be assessed by a combination of sediment toxicity testing and analysis of tissue residues in invertebrates. In many cases, however, determination of PAH tissue residues is impractical due to low body weights which can result in very high detection limits. Fish species have been shown to have sublethal effects (liver lesions) from PAHs, but because of their ability to metabolize and rapidly

excrete PAHs, fish do not accumulate significant residues in muscle tissue. Measurements of PAH metabolites in bile may provide a useful measure of exposure to PAH compounds. This may be a good approach to assessing the effectiveness of remediation in reducing the exposure to fish in the area. For assessing potential impacts of PAHs on aquatic organisms, the most useful measurement methods are toxicity testing, the determination of bioaccumulation in invertebrates and observations of histopathologic effects in benthic fish species.

PCBs, PCDDs, PCDFs

Because PCBs, PCDDs and PCDFs are not acutely lethal, standard toxicity tests are not useful measures of potential toxicity to aquatic organisms. In fact, organisms lacking aryl hydrocarbon (AH) receptors, like most invertebrates, may not exhibit any toxic response to any dosage of these compounds because the mechanism of action is incomplete. Therefore, fish are considered more sensitive than invertebrates to these compounds. Reproductive effects (through the maternal transfer of PCBs, PCDDs and PCDFs to eggs containing high concentrations lipids) are generally considered to be the most sensitive endpoints of these compounds. Further complicating the evaluation of toxicity of 2,3,7,8- TCDD/F is the fact that toxic effects of even very low dosages may be delayed until 30 - 60 days after exposure. In light of these factors, chronic toxicity tests focusing on reproductive effects may be more useful than standard LC_{50} tests for PCBs, PCDDs and PCDFs.

Because of the inherent difficulty of measuring toxicity of PCBs, PCDDs, and PCDFs, exposure is often monitored as a surrogate for toxicity. Laboratory bioaccumulation tests or in situ exposure of caged organisms may be useful in determining chemical bioavailability. Mixed function oxidase (MFO) has been used to assess exposure of fish to PCBs and 2,3,7,8-TCDD (EPA, 1993). However, bioaccumulation in and of itself provides evidence only of exposure, not of toxicity. Once bioaccumulation has been established, the observed levels of exposure should be compared to those levels reportedly associated with toxic effects, in order to determine if a significant risk exists.

The reader is referred to Section 9.3.2.1 for general guidelines on selecting measurement methods and endpoints.

9.5 TERRESTRIAL ORGANISMS AND HABITATS

This section describes environmental risk characterization for terrestrial organisms and habitats. Contaminated soil mediates most exposures to OHM in terrestrial habitats. Animals may be exposed through direct contact with contaminated soil, incidental ingestion of contaminated soil and ingestion of contaminated food. Plants may be exposed by uptake of contaminants in soil moisture or by absorption of contaminants into the roots. This section emphasizes technical considerations that are particularly relevant for terrestrial habitats, and it provides guidance for assessing impacts on terrestrial habitats in a manner that is consistent with DEP regulatory objectives.

9.5.1 Background Determination

By definition, soil concentrations that are consistent with background are considered a condition of "no significant risk of harm" for MCP purposes. Thus, a substance that is found to be consistent with background levels is not carried through the risk assessment process. Comparison of soil concentrations detected in terrestrial habitats to background conditions is essentially the same as the comparison to background in human health risk assessments. General guidance on comparison to background is covered in Section 2.0 of this guidance, and therefore it is not discussed further in this section.

9.5.2 Stage I Screening

The objective of Stage I Screening in terrestrial environments is to determine which exposure pathways must be carried through the Stage II Environmental Risk Characterization, and to identify those which can be eliminated from further consideration. The Stage I Screening Evaluation recommended in this section goes beyond determining whether an exposure pathway could lead to toxic effects.

As a first step in a Stage I Screening, this guidance recommends evaluating the size of the affected terrestrial habitat, the extent to which it is connected to other open land and the potential for effects on any areas of special concern. This step is referred to as evaluation of habitat quality. If no areas of special concern are affected and the area is not sufficient to support a balanced terrestrial community, then the need for further assessment and remediation may be ruled out.

Consideration of habitat quality prior to site-specific risk characterization ensures that quantitative risk characterizations will be applied only to those sites most likely to pose a risk to terrestrial subpopulations, populations and communities. The steps recommended for evaluating habitat significance are described in Section 9.5.2.1.

If significant exposures cannot be ruled out in the initial habitat evaluation phase, then an effects-based screening step may be conducted when soil screening criteria are available. If all soil concentrations are below the applicable screening criteria, soil exposures may be eliminated from further consideration. At present, however, the ability to conduct effects-based screening for terrestrial habitats is limited by the availability of information. Therefore, pending the development of soil screening criteria, for sites where the evaluation of habitat quality indicates the need for further assessment, the risk assessor should proceed directly to Stage II.

The decision flow diagram presented in Figure 9.3 shows how background determination and Stage I Screening can be applied in the overall risk characterization process for terrestrial habitats. The two sections that follow present more detailed discussions of Stage I habitat quality evaluation and effects-based screening.

9.5.2.1 Evaluation of Habitat Quality

The habitat evaluation described in this section applies only to terrestrial habitats. It does not apply to wetlands. Figure 9.3 shows how evaluation of habitat significance fits into the risk assessment/remediation decision process. Following is a brief description of the habitat evaluation steps:

1. If exposure of state-listed threatened or endangered species or other species of special concern is possible, a Stage II Risk Characterization should be conducted. These species are listed at 321 CMR 10.60. Significant habitats are mapped pursuant to MGL Chapter 131A.

 The Stage II Risk Characterization should include *both* exposures of State Listed Rare Wildlife *and* any other significant exposure pathways of environmental receptors. The presence or absence of any other significant exposure pathways may be evaluated by proceeding through the decision process represented in the remainder of this flow diagram.

2. If contaminant transport from surface soil to an Area of Critical Environmental Concern (ACEC) is possible, a Stage II Risk Characterization should be conducted. The presence of any other significant pathways may be evaluated by proceeding through the decision process. The Stage II Risk Characterization should include potential exposures in the ACEC as well as any other significant exposure pathways.

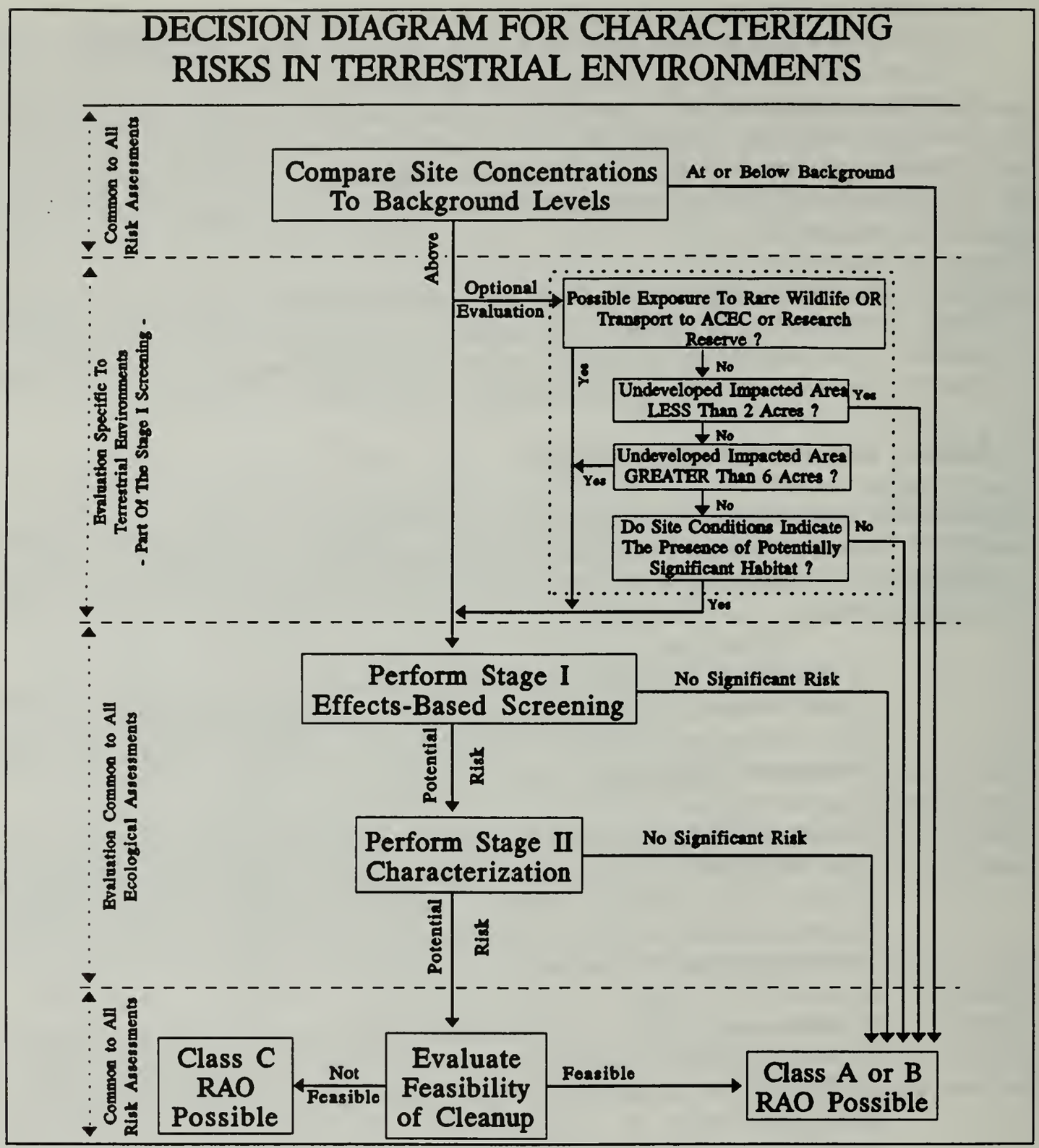

DECISION DIAGRAM FOR CHARACTERIZING RISKS IN TERRESTRIAL ENVIRONMENTS
Common to All Risk Assessments
Compare Site Concentrations To Background Levels
At or Below Background
Above
Evaluation Specific To Terrestrial Environments - Part Of The Stage I Screening -
Optional Evaluation
Possible Exposure To Rare Wildlife OR Transport to ACEC or Research Reserve ?
Yes
No
Undeveloped Impacted Area LESS Than 2 Acres ?
Yes
No
Undeveloped Impacted Area GREATER Than 6 Acres ?
Yes
No
Do Site Conditions Indicate The Presence of Potentially Significant Habitat ?
No
Yes
Evaluation Common to All Ecological Assessments
Perform Stage I Effects-Based Screening
No Significant Risk
Potential
Risk
Perform Stage II Characterization
No Significant Risk
Potential
Risk
Common to All Risk Assessments
Class C RAO Possible
Not Feasible
Evaluate Feasibility of Cleanup
Feasible
Class A or B RAO Possible

Figure 9.3

3. If the undeveloped portion[17] of the affected area is less than two acres, and neither of the two preceding criteria apply, no further assessment is necessary.

4. If the undeveloped portion of the affected area is greater than six acres, the assessment should proceed to the effects-based screening step (or, alternatively, directly to Stage II)[18]. If it is less than six but greater than two acres the assessor may either:

 (a) proceed directly to effects-based screening (or directly to Stage II), or

 (b) conduct a further evaluation to determine the presence of significant exposure pathways. Questions addressed in this evaluation should include:

 - Is the affected area connected to other open space, so that the total contiguous open space is six acres or more?
 - Does the affected area contain a unique or unusual niche for valued or protected species? An example of such a habitat is the edge of a forested area adjacent to a field.
 - Is the affected area in the vicinity of a vernal pool? The area within 150 meters may be an important part of the vernal pool habitat.
 - Does the affected area contain habitat for species the Commonwealth is trying to restore?

 This optional determination generally will require a site visit by a terrestrial ecologist. If the answer to any of these questions is yes, then the assessment should proceed to the effects-based screening step. If the answer to all of these questions is no, no further assessment is required. Evaluating the *significance*

[17]For the purposes of this screening process, undeveloped land means open land. Undeveloped land is characterized by the presence of native vegetation, and does not include landscaped residential and commercial parcels, landscaped parks or golf courses.

[18]At present, there is no consensus on soil benchmark concentrations that can be used as general screening criteria without a site-specific justification. Therefore, at sites where the habitat quality evaluation indicates the need for further assessment, in the absence of screening criteria, the risk characterization should proceed directly to Stage II.

of complete exposure pathways in terrestrial habitats is a crucial step in many cases. While complete exposure pathways exist wherever soil is contaminated, many sites will not warrant further evaluation, given the nature and/of number of receptors exposed.

5. If significant exposure is not ruled out by considering the size of the site and the nature of the surrounding land as specified in the previous decision points, then the assessor should conclude that a potentially significant exposure pathway exists or may exist, and proceed either to the effects-based screening step or to the Stage II Environmental Risk Characterization.

9.5.2.2 Effects-based Screening (Terrestrial Habitats)

Benchmark values analogous to those used for screening of aquatic exposure pathways are not available for terrestrial habitat screening at this time. As a result, it is not possible to rule out the need for a Stage II Environmental Risk Characterization using simple effects-based screening criteria. USEPA is currently evaluating options for developing "Ecotox Thresholds" for soil. Depending upon their derivation, those concentrations may be appropriate for screening purposes in MCP Risk Characterizations. When the Ecotox Thresholds are finalized, DEP will evaluate their applicability as soil screening criteria in the Stage I Environmental Screening. For the present, exposure pathways must be evaluated in a Stage II Risk Characterization if the risk of harm cannot be confidently ruled out by the habitat evaluation procedure outlined in 9.5.2.1. The Stage II Risk Characterization steps are described in the following section.

9.5.3 Stage II Environmental Risk Characterization (Terrestrial Organisms and Habitats)

The focus and scope of Stage II Environmental Risk Characterizations for terrestrial habitats are likely to vary widely from site to site. Considering the lack of readily available numerical screening criteria, Stage I Environmental Screening will not eliminate all of the sites that do not really warrant an extensive quantitative assessment. Ideally, those situations should be identified early in Stage II Environmental Risk Characterizations.

When site concentrations are judged to be relatively low, the risk assessor should attempt to structure the Stage II Environmental Risk Characterization so that relatively simple, conservative assessment methods are used initially to determine whether the risks associated with site concentrations are potentially significant. A simple assessment may demonstrate that a condition of "No Significant Risk" exists, within a short time frame and at a relatively low cost.

For example, doses at which no adverse effects have been observed may be compared with conservative estimates of doses from exposures to contaminants at or from the site. This approach can often be used to determine whether significant risk of harm can be quickly and inexpensively ruled out. Such evaluations may be thought of as an extension of Stage I Environmental Screening procedures. These screening-type evaluations are included in Stage II in this guidance primarily because proper application requires consideration of site-specific conditions by an ecological risk assessor. The risk assessor must exercise professional judgement in determining the extent to which such extended screening-level analyses should be applied at any one site, in identifying data and methods appropriate for use in such evaluations.

9.5.3.1 Sampling and Analytical Considerations

Estimating soil exposure point concentrations requires consideration of contaminant distribution, detected concentrations, and the behavioral patterns of mobile organisms that determine the frequency, intensity and locations of exposure. Soil contamination is seldom distributed uniformly, and soil contaminant concentrations often span orders of magnitude. Careful planning is critical to ensure that site sampling efforts produce the data needed to accurately characterize risks from soil exposure. Therefore, coordination of sampling and assessment plans is crucial.

In the MCP site assessment/cleanup process, some analytical data, often a large amount of data, are already available when an environmental risk characterization is initiated. Nevertheless, additional sampling may be necessary to meet the data requirements of the environmental risk characterization. In any case, ecological assessment and environmental sampling should be an iterative process, particularly in terrestrial habitats. Potential receptors and exposures should always be considered when soil sampling plans are developed. After initial samples have been collected, the results should be used to identify the species and communities potentially at risk. Once the receptors of concern are identified, additional sampling may be necessary to accurately characterize exposure for those organisms.

9.5.3.2 Problem Formulation

In the Problem Formulation phase, the risk assessor should identify a combination of measurement and assessment endpoints that will lead to and support a conclusion regarding the risk of ecological harm at the site in question. The following two sections discuss assessment considerations of particular importance for terrestrial habitats.

Identification of Assessment Endpoints

The risk characterization for a specific site may evaluate any number and combination of assessment endpoints. Usually it is impractical to quantify the risk of all potential effects in a terrestrial environment, so a few representative assessment endpoints are selected. The combination of endpoints selected should represent all exposure pathways of concern, so that cleanup decisions based on the assessment results will address all existing and potentially significant risks of harm. When identifying potential assessment endpoints, the risk assessor should identify the types of organisms that are most susceptible to OHM at or from the site.

The types of organisms likely to be exposed in terrestrial environments and the pathways by which they may be exposed are briefly outlined in the section that immediately follows. Subsequently, considerations in identifying the likely toxic effects of the contaminants of concern are described.

Identifying Potential Exposure Pathways/Receptors in Terrestrial Habitats

The species that are present in the vicinity of a site, or that would be present in the absence of contamination, depend upon the characteristics of the habitat in the area. A species can only survive and thrive in an area that meets its habitat requirements. Thus, potentially exposed species can be identified through an evaluation of habitat features. Habitat evaluation techniques involve the inventory and evaluation of environmental resources and determination of how well the environmental conditions meet the needs of wildlife. References related to terrestrial habitat evaluation are included at the end of this section (9.5).

A brief summary of the types of organisms and exposure pathways of potential concern follows:

Vegetation

Uptake of contaminants directly from soil by plant roots (shrubs, trees, etc.) may harm the plant community itself as well as provide an exposure opportunity for organisms that feed on plants. Patches of soil contamination may affect plants through soil pore water contamination. If the groundwater is contaminated within the study area and a shallow water table exists, the potential for exposure to groundwater should be considered for terrestrial plants.

Terrestrial Invertebrates

Soil moisture containing dissolved contaminants is an important exposure medium for soil invertebrates at sites. In addition, soil invertebrates live in direct contact with soil. Earthworms

ingest large quantities of soil during their normal life cycle. Soil invertebrates may encounter elevated concentrations of chemicals in localized surface soil areas, so the spatial scale of exposure areas for individual organisms may be small relative to exposure areas of concern for larger, more mobile species.

Amphibians and Reptiles

Dermal contact with contaminated soil, sediment or surface water and ingestion of contaminated food are important routes of exposure for amphibians and reptiles. Other potential pathways include incidental soil ingestion and surface water ingestion.

Mammals and birds

Mammals and birds visiting or living at the site may be exposed to contamination by ingestion of contaminated food and incidental ingestion of contaminated soil. Carnivorous and piscivorous species are often at greatest risk when contaminants that bioaccumulate are present.

Although food chain exposures are a primary concern for many birds and mammals, dermal contact and incidental ingestion of soil may also be important for some species of mammals. In addition, some birds may ingest a significant amount of soil because it functions as grit.

In areas where soil is contaminated by volatile organic compounds, inhalation may be an important exposure pathway, particularly for burrowing animals. However, it may not be possible to quantify such exposures with reasonable accuracy. Where inhalation by burrowing animals may be significant, the risk assessment should address this pathway qualitatively.

Identifying Toxic Effects of the Contaminants of Concern

In many cases, identifying potential toxic effects is less straightforward than identifying potential receptors. The toxic effects of many substances have only been studied for a few species. As a result, there may be no dose-response information for the specific contaminants and species of concern at many sites. To an extent, this problem can be minimized by considering the availability of toxicological data when selecting the assessment endpoint species.

The availability of species-specific toxicological information is not, however, the only consideration in identifying endpoint species, so toxicity data may not be available for some endpoints. When data on the toxic effects of the contaminants of concern are not available for the species likely to be exposed at the site, it may nevertheless be appropriate to evaluate effects on those species as assessment endpoints, rather than ruling out the possibility immediately because of a lack of data. In the absence of species-specific toxicity data, interspecies extrapolation may be appropriate. Furthermore, if toxicity data are not available for a specific compound of concern, toxicity data on related substances should be considered. The risk assessor should use

professional judgment in determining whether the available information supports such extrapolations.

Assessing the Susceptibility of Receptors

The susceptibility of an organism to harmful effects from contamination depends on the *intensity of the exposure* and the *toxicity of the contamination* combined. The level of exposure is therefore an important factor in deciding which species or groups of species to use for the assessment endpoint. The potential for exposure by various routes (inhalation, ingestion and dermal contact) depends upon the animal's activity patterns. Foraging, nesting, burrowing and dust bathing are examples of activities that result in exposure to soil contaminants.

The size and location of a species' home range relative to the area of contamination is another important consideration in identifying potentially exposed species, and in selecting assessment endpoints. Ideally, the home range of the assessment endpoint species should be equal to or less than the area of contamination, so that the exposures that are quantified represent the highest exposures experienced by any species in the vicinity of the site. Nevertheless, when identifying effects on wildlife species that could potentially be assessment endpoints, species with relatively large home-ranges should not necessarily be eliminated from consideration, because home range is only one of several factors to be considered in selecting endpoints. If a species spends only a portion of its time in a contaminated area, but is very sensitive to the contaminants of concern, or experiences very high exposures when it is in the area, it may be important to evaluate those short but intense exposures in the risk characterization. Thus, a relatively large home range does not by itself justify ruling out a species as a candidate for an assessment endpoint.

Measurement Methods/Endpoints

A number of investigatory approaches are available for evaluating the ecological effects of hazardous materials on terrestrial habitats and organisms. These include the benchmark approach, the toxicity quotient method, toxicity tests, tissue analysis and field surveys. The result of a particular test or analysis is a measurement endpoint. Measurement methods for a specific site should be selected so that the results can be related to an assessment endpoint.

In selecting measurement methods, the risk assessor should consider the strength of the links between possible measurement endpoints and the assessment endpoints that were selected for the site. For a particular test to be useful, it should provide results from which subpopulation, community level or system-wide ecological effects (represented by the assessment endpoints) can be interpreted. Furthermore, the method should be sensitive enough to detect changes in environmental conditions that may affect the exposed

subpopulation. Following is a brief discussion of the applicability of each measurement approach:

Benchmark Approach

The benchmark approach involves comparing concentrations in environmental media or in appropriate tissue samples to concentrations of concern published in the literature. Few, if any, benchmark values are currently available for terrestrial evaluations. However, as new information becomes available in the future, it should be incorporated into the terrestrial assessment process.

Field Studies

A field study may involve conducting a census to determine population size, number of species, or to evaluate diversity. Field surveys can provide direct and definitive evidence of adverse ecological effects. They are especially important for terrestrial habitats because, in comparison to aquatic habitats, there are fewer available standardized toxicity tests and benchmark values. Field studies can provide an important reality check on the risk estimates resulting from the toxicity quotient method (discussed below).

Population changes or fluctuations resulting from causes other than exposure to contaminants may be confounding factors in measuring impacts from sites. Obtaining an accurate estimate of a population size requires consideration of the ecology and behavior of the species, and the natural variability of the population. To assess the status of naturally fluctuating populations of short-lived species, the collection of demographic parameters, such as sex and age ratios[19], natality, survival and mortality rates, may be critical in judging the impact of contaminants. Any population sampling requires the assumption that mortality and recruitment during the sampling period are small, and that all members of the population have an equal chance of being sampled. (McBee 1988).

A decision to use a field study to evaluate potential population changes resulting from contamination should consider whether the population in question is a source or sink population. A source population is the main population which supplies the surrounding population with immigrants. A loss of source population can have a large impact on the overall regional population size. Sink populations exist due totally to immigration from source populations. The size of a sink population may be misleading, since individuals

[19]Sex ratios will indicate whether or not populations are present in numbers and proportions sufficient for normal reproductive activity. Age ratios provide information on natality, mortality and survival rates.

that are adversely affected by chemicals and eliminated by mortality may be quickly replaced through immigration, masking evidence of adverse effects/ecological harm. Thus, the size of a sink population is not necessarily a useful indicator of harm.

Toxicity Tests

Toxicity tests have been developed and applied in site assessments for a number of lower trophic level terrestrial receptors. Earthworm bioassays are the most common standardized procedures; both laboratory and field procedures have been used for these tests. Standardized plant toxicity tests are also available.

Responses observed in toxicity tests are generally considered organism-level effects; they may not always accurately predict effects that would occur in populations in nature. Therefore, the results should be extrapolated[20] to estimate population or community-level effects from organism-level effects; to assess field conditions based on laboratory conditions; and to predict effects on species other than those tested and chronic effects from acute studies. If the results of a toxicity test can clearly be linked to an assessment endpoint, the test can play an important role in the assessment by providing direct evidence of adverse effects.

The substance or substances that actually cause the toxic effects cannot necessarily be identified in soils containing a mixture of contaminants. No test method for apportioning toxicity among multiple constituents is currently available for soil. Terrestrial toxicity tests are less likely to be affected by non site-related contaminants than are aquatic tests. Nevertheless, when a mixture of contaminants is present in the soil, it may be difficult to translate the results of a toxicity test into remediation goals.

When the measurement endpoint of a toxicity test is a sublethal organism level effect, the risk assessor should determine whether that effect is related to assessment endpoints that represent population or community level effects. Not all sublethal effects are expected to translate into a population reduction or a change in community structure. Reproductive effects are examples of sublethal responses that are likely to have population level impacts.

For an overview of toxicity tests that have been used for various organisms, the reader is referred to *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory*

[20]Extrapolation of toxicity test results does not necessarily imply a quantitative adjustment of dose-response data. It may simply mean assuming that the results of a toxicity tests reasonably predict or represent actual effects at the site.

Reference Document (Warren-Hicks et al., 1988) and *Evaluation of Terrestrial Indicators for Use in Ecological Assessments at Hazardous Waste Sites* (EPA 1992b).

Tissue Residue Analysis

When contaminants of concern are known to bioaccumulate[21], residue analysis provides useful information on exposure. In some cases, tissue residue concentrations can be used directly with published information on toxic levels to characterize risk. However, toxicity information directly applicable to tissue concentrations is generally unavailable, and residue analysis is more often used in conjunction with other assessment approaches. When used with the toxicity quotient method, tissue concentrations for prey species can eliminate the need for using models and exposure assumptions about which there is substantial uncertainty. When tissue concentrations can be obtained for the assessment endpoint species, they can provide a reality check on assumptions about exposure and uptake of bioaccumulating substances.

Toxicity Quotient Method

The toxicity quotient method involves calculating the ratio of the average daily dose from exposure to contaminants at or from the site to a no observed adverse effects level (NOAEL) or lowest observed adverse effects level (LOAEL) obtained from scientific literature or derived from published toxicity data. The toxicity quotient method has been widely used for terrestrial assessments mainly because other options are limited. Standardized toxicity tests for terrestrial organisms have not been extensively developed, and benchmark soil concentrations are not available.

When the site-related contaminant dose is based on a direct measure of exposure, such as a measure of the contaminant levels in a food source, the accuracy of the risk estimate depends primarily on the reliability of the NOAEL or LOAEL used. When the dose received at the site is estimated (modeled) using uptake assumptions with chemical concentrations measured in environmental media, the accuracy of the risk estimate depends on both the exposure estimate and the NOAEL or LOAEL used. The uncertainty is greater for risk estimates based on estimated doses than for those derived from direct measurements of exposure. In either case, substantial professional judgment is required, particularly in selecting exposure factors and NOAELs or LOAELs, since a database of toxicity values for wildlife has not been published to date.

When exposure is estimated from environmental concentrations, the toxicity quotient method is sometimes referred to as a predictive approach. Estimates of exposure can be

[21]Substances that are known to bioaccumulate include mercury, cadmium, lead, PCBs, and some pesticides.

useful when direct measurements are impossible or impractical to obtain. However, the use of exposure models introduces a high level of uncertainty. Based on a comparison of the results of predictive methods with direct measurement, investigators have reported that predictive methods may substantially overestimate risk for organisms at higher trophic levels (Menzie et. al. 1992). Nevertheless, predictive models are an option when more accurate information and procedures are not available.

The reader is referred to Section 9.3.2.1 for guidelines on the selection of measurement methods and endpoints.

9.5.3.3 Analysis Phase

The analysis phase involves performing the measurements necessary to evaluate the measurement endpoints. This phase includes quantitative assessment of both exposure and effects for the selected assessment endpoints. These components are discussed briefly in the paragraphs that follow.

Exposure Assessment

The potential for exposure of an organism to soil contamination within its habitat depends upon (1) the organism's activity patterns (2) the extent to which its home range corresponds with the contaminated area and (3) the concentration distribution(s) in the contaminated area. A comprehensive discussion of the first of these is provided in EPA's *Wildlife Exposure Factors Handbook* (EPA 1994). This section addresses the latter two factors, home range and contaminant distribution. Estimation of exposure point concentrations is also discussed.

Home Range

The extent of overlap of an animal's home range with the area of contamination is one determinant of exposure frequency. The greater the overlap, the higher the frequency of exposure to contamination. If the contaminated area comprises only a fraction of the area over which the animal ranges, exposure to contaminated soil may be less frequent than if the entire home range were contaminated. For species which migrate seasonally, temporal home range effects should also be considered.

Risk assessors should be cautious when estimating frequency of exposure in areas that comprise only a fraction of an species' home range. One cannot necessarily assume that exposure frequency decreases in direct proportion to the fraction of home range that is contaminated. One reason is that the probability of exposure may not be equal for all locations within the home range. Another reason for caution is that an animal's actual territory may be smaller than it otherwise might be due to limited open space and/or a patchy landscape.

Characterizing Contaminant Distribution

The vertical and horizontal distribution of contamination in the soil determines which species are likely to be exposed, as well as the likely levels of exposure. Some species are exposed only to surface or near-surface soil, while others may burrow into the soil and be exposed to contaminants at depth. Thus, soil samples should be collected from specific depths of concern, based on existing data and potential exposures.

The horizontal distribution of chemical concentrations within a given soil stratum determines the range of concentrations to which different sessile organisms may be exposed. It also represents the concentrations to which mobile organisms are likely to be exposed over time. In order to assess both chronic and subchronic exposures, a sufficient number of samples must be collected from within the exposure area to obtain an average concentration representative of a mobile organism's level of exposure over time.

Estimating Soil Exposure Point Concentrations

Exposure point concentration estimates used in the risk characterization should be consistent with the risk characterization method(s) being used. For comparison to a benchmark value or standard, the site concentration should be calculated in a manner that corresponds with the derivation of the benchmark value in question.

For chronic and subchronic exposures of mobile organisms (birds, mammals, reptiles and amphibians), the exposure point concentration should be an estimate of the arithmetic mean concentration to which the organism is exposed over the exposure period. The average soil concentration in the exposure area may be used as an estimate of the average exposure concentration over time, assuming that (1) the data from the exposure area represent a random or systematically collected sample and (2) at any one time, an organism of concern is equally likely to contact soil at all locations in the exposure area.

When exposure is likely to be more frequent in some portions of the contaminated area than others, or when more samples have been collected from certain locations, a weighted average may provide a more accurate estimate of the average concentration contacted over time. Often, sampling efforts at sites focus on the areas known (or believed) to be most heavily contaminated, and sampling patterns are not systematic or random within the exposure area. In such cases, an area-weighted average may provide a better exposure point concentration estimate.

The other assumption required in order to use an average soil concentration is that exposure is equally likely at all sampling locations. This assumption may not hold true if the habitat characteristics vary within the sampled area, or if for any other reason the

organism of concern is less likely to frequent some locations than others within the area sampled. In this case, a weighted average may be calculated to reflect different exposure frequencies. Weighted averages are discussed in more detail in Section 7.3.4.5 of this guidance document.

There are several exceptions to the general practice of using the average as the exposure point concentration. The highest detected value is recommended for use when: (1) acute exposure is being quantified, (2) a screening assessment is being conducted using conservative estimates of all exposure factors, or (3) the data are inadequate to characterize the exposure area, and there is a high level of uncertainty about the true average value.

Ecological Effects Assessment

The effects assessment component establishes a quantitative link between contaminant concentrations and adverse effects in receptors. Measurement procedures used to evaluate the probability and magnitude of adverse effects vary widely, depending on the specific endpoints selected for the assessment.

For field studies alone, numerous measurement approaches are available, and a comprehensive treatment is beyond the scope of this document. The reader is referred to *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document* (Warren-Hicks et al. 1988) for guidance on planning and conducting field studies and toxicity studies, and for references providing more detailed information.

Toxicity tests provide direct evidence of a quantitative link between the contaminants and organisms used in the test. Ideally, to evaluate the toxicity of soil contaminants at a site, contaminated soil from areas to the site representing a gradient of contaminant conditions should be tested, i.e. high, medium, low and non-detect concentrations. The use of indigenous organisms, rather than stock laboratory test organisms, reduces the uncertainty inherent in using toxicity test results to predict actual effects at the site. The use of field-based toxicity tests, however, is not an option for evaluating dose/response relationships for birds and mammals, and is generally limited to evaluating effects on plants, invertebrates and microbial populations, which may not always be endpoint species.

Literature reviews can provide the dose/response information needed to characterize risks using the toxicity quotient approach. Guidance on using literature data to derive toxicity values for use in an assessment is presented in Section 9.5.3.6.

9.5.3.4 Risk Characterization Phase

In this phase, the results of the measurements are evaluated to determine whether they support a conclusion of no significant risk for each assessment endpoint. When multiple measurements have been conducted and the results are not in concurrence, the risk assessor should determine whether the "weight of evidence" indicates a significant risk of harm to the environment. Section 9.3.2.3 contains guidelines for weight of evidence evaluations.

9.5.3.5 Guidance for Characterizing Risk Using the Toxicity Quotient Method

The method outlined here is similar to the procedure used in human health risk assessments to characterize non-cancer health effects. The measurement endpoint is a quotient representing the likelihood of a particular effect from a single substance on a single species. In selecting the appropriate target species and toxic effect, the strength of the relationship between the effect measured and the assessment endpoint should be considered carefully. For example, it may be difficult to link sublethal effects with a reduction in population size.

Dose Response Evaluation for the Toxicity Quotient Method

In the toxicity quotient method, a measurement or an estimate of the exposure being evaluated is used with toxicity data from the literature to characterize risk. The ratio between a site-related exposure dose for a particular animal and an allowable dose obtained from the literature is referred to as the hazard quotient. Published toxicity values are most often "lowest observed adverse effect levels" (LOAELs) based on a laboratory toxicity study involving a species assumed to be of similar sensitivity to the evaluation species. For an environmental risk characterization, a corresponding "no observed adverse effect level" (NOAEL) should also be identified or estimated.

When the toxicity quotient method is used for quantitative risk assessment (in contrast with the screening procedure described earlier), adjustment of the LOAEL for interspecies sensitivity may be appropriate. Unfortunately, data on differences in sensitivity among wildlife species are extremely limited. As a result, such results require applying substantial professional judgment. However, the assessment report should present a compelling justification when an adjustment is made for a less sensitive receptor species.

Fish and wildlife LOAEL and NOAEL toxicity values for the chemicals of concern should be selected when possible, from dose/response studies on the species selected for the environmental risk characterization. Where these are not available, information from phylogenetically similar species should be used. For example, if data are available from the same taxonomic family, these should be used rather than data from a different family. The

U.S. Fish and Wildlife Service (USFWS) biological reviews and other applicable wildlife studies should serve as primary sources of information.

The identification of appropriate toxicity values may require applying extensive professional judgment, and the rationale for the values selected should be fully documented in the risk characterization report. The following text provides an *example* of an acceptable procedure for identifying NOAELs and LOAELs to be used in the toxicity quotient method:

> If an appropriate state or federal agency has proposed a toxicity value as a criterion for the protection of wildlife, that value should be used unless it is clearly not applicable for the specific case, and a more appropriate value is identified.

In the absence of such proposed criteria and if data are available on LOAELs and NOAELs for the receptor species, or for species that are phylogenetically similar to the selected receptor species (e.g. from the same family of birds or mammals), the lowest LOAEL and highest NOAEL are selected. DEP recommends using the highest NOAEL, rather than the lowest, because a NOAEL may be much lower than the actual lowest effect level. A NOAEL represents a dose that causes no effect, but, by itself, it provide no information on how much higher the concentration has to be to produce an effect. For this reason, DEP recommends using the highest NOAEL when data on the species of concern or species within the same family are used.

If LOAELs and NOAELs for phylogenetically similar species are unavailable, the assessment adjusts values for other species (as closely related as possible) by dividing by a factor of 10 (or other factor if data are available) to account for extrapolations between families or orders. When several studies are available, the LOAEL and NOAEL based on the species and effect most relevant to the assessment endpoint are used.

For calculating toxicity values from data for sub-chronic tests (e.g., acute data) the resultant LOAEL or NOAEL values are divided by an additional factor of 10. This is consistent with what is done in deriving human health reference dose (RfD) values.

In cases where LOAELs or NOAELs are available as a dietary concentration (e.g. mg contaminant per kg food), a consumption rate is estimated based on various food intake summaries and a corresponding daily LOAEL or NOAEL dose is calculated. This consumption rate is generally expressed as a percentage of the animal's body weight on a wet weight basis or in units of g/g/day (grams of food per gram of body weight per day).

Again, this procedure is offered as an example, and is not intended to preclude the use of an alternative.

Exposure Assessment for the Toxicity Quotient Method

In the exposure assessment, the exposure pathways to be evaluated are identified, and the magnitude, frequency and duration of exposure are estimated. It is often difficult to obtain the information needed to derive reliable estimates of exposure magnitude for many terrestrial species from the available literature. The EPA has compiled extensive exposure data in the *Wildlife Exposure Factors Handbook* (EPA 1994), which should serve as a primary source of information for wildlife exposure assessment.

For chronic and subchronic exposure assessments, the exposure point concentration should represent a time weighted average of the concentration to which the organism is exposed during the exposure period. Assuming that at any one time, exposure of a mobile organism is equally likely at any point in the exposure area and that sampling locations are random, the arithmetic mean of soil concentrations in that area may be used to represent the mean exposure over time. If sampling locations are not randomly distributed, area weighting would allow the spatial average to be used as a surrogate for the temporal average. For a more thorough discussion of this approach, the reader is referred to the section on Exposure Point Concentrations in this document.

To estimate the frequency of exposure, the proportion of time the target species spends in the contaminated area should be considered. Species whose home range is less than or equal to the area of contamination should be selected if possible. If the assessment only evaluates species that have home ranges larger than the site, their relatively low exposure frequency will result in low risk estimates relative to those that would be predicted for species exposed on a regular and continuing basis.

An overview of terrestrial ecosystem models is provided in Models for Ecological Risk Assessment: A State of the Art Review. (Emlen 1989). Where appropriate, the EPA's Terrestrial Ecosystem Exposure Assessment Model (EPA 1989d) should be considered.

Risk Characterization for the Toxicity Quotient Method

When the quotient method is used for quantitative assessment (as opposed to effects-based screening), risk should be characterized by calculating the ratios of the site-related dose to the most appropriate values of **both** the lowest observed adverse effect level (LOAEL) **and** the no observed adverse effect level (NOAEL) published in the literature. The expressions for these ratios are:

$$\text{Hazard quotient}_{NOAEL} = \frac{\text{Site exposure dose (or tissue conc.)}}{\text{NOAEL}}$$

$$\text{Hazard quotient}_{LOAEL} = \frac{\text{Site exposure dose (or tissue conc.)}}{\text{LOAEL}}$$

BWSC recommends the following general rules of thumb for using hazard quotients to characterize risks:

- When the site dose exceeds the LOAEL and the LOAEL-based hazard quotient is greater than one, it is reasonable to conclude that the quotient evaluation method provides evidence of harm.

- When the site dose is lower than the NOAEL and the NOAEL-based hazard quotient is less than one, the risk assessor may reasonably conclude that the quotient method does not provide evidence of harm.
- When the site dose is greater than the NOAEL but less than the LOAEL, no conclusion may be reached based on the predictive method alone, and additional assessment efforts are necessary to determine whether the oil or hazardous material has harmed or may harm the environment.

In a risk characterization using the toxicity quotient method, the relative magnitudes of uncertainty from all sources should be discussed. The level of uncertainty associated with the toxicity quotient method depends in part upon whether exposures were measured directly or estimated from environmental concentrations using a series of exposure factor assumptions. When exposures are measured directly, the uncertainty about the risk estimate depends primarily on the accuracy of the NOAEL or LOAEL used to characterize risk. However, when exposures are estimated, additional sources of uncertainty are introduced.

9.5.3.6 Integrated Approach to Measurement Method Selection and Analysis

The risk assessment process outlined in Section 9.3 portrays a rather formal sequential procedure, progressing from the selection of measurement methods at the end of the Problem Formulation phase to the collection and analysis of data, and then to risk characterization. At some sites, it may be more efficient to conduct preliminary analysis phase investigations (i.e. collect additional data, compare concentrations to available benchmarks), and use the resultant information to determine the kinds of measurements needed to evaluate exposure and risk. Figure 9.4 illustrates an *example* of a more iterative decision process that integrates method selection with analysis activities.

This approach allows the risk assessor to evaluate measurement endpoints sequentially. The simplest measurements are conducted first and the more complex measurements are conducted later. If the results of the earlier methods provide a clear indication that a condition of no significant risk exists, or that significant risk does exist, the need for more complex, costly measurements is eliminated.

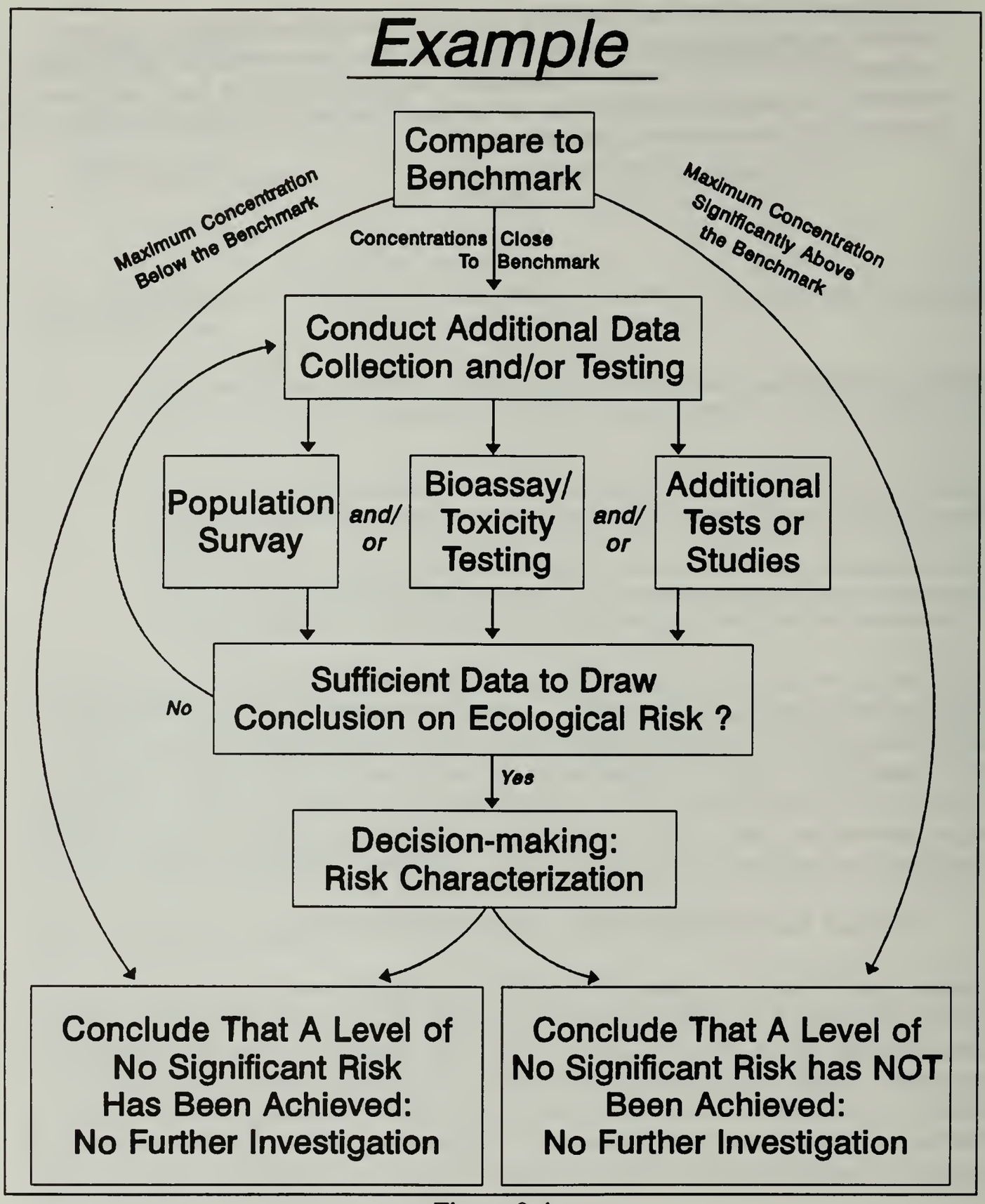

Example
Compare to Benchmark
Maximum Concentration Below the Benchmark
Concentrations Close To Benchmark
Maximum Concentration Significantly Above the Benchmark
Conduct Additional Data Collection and/or Testing
Population Survay
and/ or
Bioassay/ Toxicity Testing
and/ or
Additional Tests or Studies
No
Sufficient Data to Draw Conclusion on Ecological Risk ?
Yes
Decision-making: Risk Characterization
Conclude That A Level of No Significant Risk Has Been Achieved: No Further Investigation
Conclude That A Level of No Significant Risk has NOT Been Achieved: No Further Investigation

Figure 9-4

Selected Terrestrial Habitat Evaluation References

Adamus, P.R., L.T. Stockwell, W.J. Clairain, Jr., M.E. Morrow, L.P. Rozas, and R.D. Smith. 1991. Wetland Evaluation Technique (WET). Volume 1: Literature Review and Evaluation Rationale. U.S. Army Corps of Engineers. Waterways Experiment Station. Vicksburg, MI. Wetlands Research Program Technical Report WRP-DE-2. 287pp.

Atkinson, S.F. 1985. Habitat-Based Methods for Biological Impact Assessment. The Environmental Professional. 7:265-282.

Cooperrider, A.Y., R.J. Boyd, and H.R. Stuart (eds). 1986. Inventory and Monitoring of Wildlife Habitat. U. S. Department of the Interior, Bureau of Land Management Service Center, Denver, CO. 858 pp.

Davis, D.E. 1982. CRC Handbook of Census Methods for Terrestrial Vertebrates. CRC Press, Boca Raton, FL. 424 pp.

Hays, R.L., C. Summers, and W. Seitz. 1981. Estimating Wildlife Habitat Variables. U.S. Fish and Wildlife Service. FWS/OBS-81/47. 111 pp.

Ralph, C.J. and J.M. Scott (eds). 1981. Estimating Numbers of Terrestrial Birds. Studies in Avian Biology. 6:1-630.

Reimold, R.J. 1994 (in press), Wetlands Functions and Values. in D.M. Dent, ed. Applied Wetlands Science and Technology. Lewis Publishers. Chelsea, MI.

Schemnitz, S.D. (ed). 1980. Wildlife Management Techniques Manual, Fourth Edition Revised. The Wildlife Society, Washington, D.C. 686 pp.

Schroeder, R.L. 1987. Community models for wildlife impact assessment: a review of concepts and approaches. National Ecology Center. U.S. Fish and Wildlife Service. Washington, D.C. Biological Report 87(2). 41pp.

Short, H.L. 1982. Development and use of a habitat gradient model to evaluate wildlife habitat. in: Transactions of the Forty-Seventh North American Wildlife and Natural Resources Conference. Wildlife Management Institute. Washington, D.C. pp. 57-72.

U.S. Environmental Protection Agency. 1988. Hazard Evaluation Division, Standard Evaluation Procedure: Guidance Document for Conducting Terrestrial Field Studies. EPA 540/09-88-109.

U.S. Environmental Protection Agency. 1989. Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference. EPA/600/3-89/013.

U.S. Environmental Protection Agency. 1992. Evaluation of Terrestrial Indicators for use in Ecological Assessments at Hazardous Waste Sites. EPA/600/R-92/183.

U.S. Fish and Wildlife Service. 1980. Habitat Evaluation Procedures (HEP). ESM 102.

U.S. Fish and Wildlife Service. 1986. Draft Type B Technical Information Document: Recommendations

9.6 WETLAND HABITATS

Wetlands provide numerous environmental functions, including flood control, groundwater recharge, removal and cycling of sediments, organic material and nutrients from surface water, and bank/shoreline stabilization. Only a few of these functions are likely to be impaired by contamination. This guidance focuses on the effects of site contaminants on a wetland's function as a wildlife habitat and on the organisms that depend on it. Nutrient cycling is another wetland function that could also be adversely affected by contamination. Although the other functions are less likely to be affected directly by contamination, they can be seriously impaired or damaged by site investigation or cleanup activities. **Therefore, the risk of physical damage to wetland habitats must be considered when planning site investigation and cleanup activities, although risks directly associated with remediation activities are addressed during Phase III.**

Wetlands include:

(1) all permanent surface water and the land underneath;

(2) all areas flooded along such waters during the hypothetical 100 year storm event;

(3) all "vegetated wetlands" such as bogs and swamps, including wooded swamps, marshes and wet meadows; and

(4) all seasonal (intermittent) streams draining from a wetland.

These four wetland classes are broad; they could be further categorized by applying other classification systems, such as that developed by the U.S. Fish and Wildlife Service (Cowardin et al. 1979).

9.6.1 Wetland Classification and Delineation

Delineation is considered at a number of decision points in the MCP process, including:

* Tier classification, which determines the priority of the site and allocation of DEP staff for oversight,

* Selection of the appropriate assessment method, in which the presence of sediment contamination within the boundary of a wetland precludes the use of Method 1 alone, and

* Stage I Screening, because the recommended Stage I Screening procedures for wetland sediments differs from that for terrestrial soils.

Classification and delineation both apply to:

* Environmental risk characterization, in which the nature of the wetland determines the potential receptors and

* Phase III feasibility studies, in which the habitat value of a wetland as well as the potential to replicate it may have to be considered in choosing remediation techniques.

The term "wetlands" is a very broad one, encompassing lands and waters that are components of a wide variety of habitats. The definition of wetlands in the MCP includes areas subject to the Wetlands Protection Act and the regulations published under the Massachusetts Clean Water Act and the federal Water Pollution Control Act. Areas subject to the Wetlands Protection Act include:

(a)	any bank		the ocean
	any freshwater wetland		any estuary
	any coastal wetland		any creek
	any beach		any river
	any dune	bordering	any stream
	any flat	on	any pond or
	any marsh or		any lake
	any swamp		

(b) Land under any of the water bodies listed above
(c) Land subject to tidal action
(d) Land subject to coastal storm flowage
(e) Land subject to flooding

The U.S. Fisheries and Wildlife service has defined wetlands somewhat more narrowly, as lands transitional between terrestrial and aquatic systems, where the water table is usually at or near the surface or the land is covered by shallow water. (Cowardin *et al.*, U.S. Fish and Wildlife Service, 1979).

For the purpose of considering applicable standards, it is important to apply the definition of wetlands that is consistent with the standard in question. However,

regulations corresponding to specific wetland definitions may be considered suitably analogous standards in other wetland areas.

Given the transitional nature of wetlands between terrestrial and aquatic systems, sediment and/or soil may be present in a given wetland. The MCP (310 CMR 40.0006) gives the following definition for sediment:

> *Sediment means all detrital and inorganic or organic matter situated on the bottom of lakes, ponds, streams, rivers, the ocean, or other surface water bodies. Sediments are found:*
>
> > *(a) in tidal waters below the mean high waterline as defined in 310 CMR 10.23; and*
> >
> > *(b) below the upper boundary of a bank, as defined in 310 CMR 10.54(2) which abuts and confines a water body.*

All other unconsolidated earth in wetlands, including the 10 year floodplain, is considered soil. In general, exposure to contaminated sediment should be evaluated with reference to Section 9.4 on Aquatic Organisms and Habitats, and exposures to contaminated soil should be evaluated with reference to Section 9.5 on Terrestrial Habitats and Organisms. As noted in a previous section, the risk characterization must also address exposures of the terrestrial birds and mammals which may eat, drink or nest at surface water bodies.

9.6.2 Wetlands Protection Considerations

The scope and rigor of the Wetlands Protection Act and corresponding regulations provide an indication of the biological and societal value placed on wetlands, especially regulated wetlands, open water, vernal pools and rare species habitats. The regulations protect all vertebrate wildlife species which use wetlands (as well as rare and endangered invertebrates). The regulations forbid any adverse effects on any amount of vernal pool habitat or any short or long term effect on the local population of a rare species. Adverse effects on wildlife habitat may include direct and indirect effects on food and shelter as well as on breeding, migratory and overwintering areas. Potential causes of adverse effects include alteration in water quality or in plant community structure.

The habitats and ranges of exposed organisms may not coincide with legally defined delineations. When evaluating exposures of biota and habitats, the focus should be on the distribution of contamination and the habitats of the exposed organisms, so that all locations where organisms are exposed are considered. Various wetland definitions are

useful in identifying organism, habitats and functions of potential concern, but they may not always provide appropriate site investigation boundaries.

9.6.3 Stage I Environmental Screening

As is the case for aquatic and terrestrial habitats, Stage I Screening identifies all potential receptor groups and exposure pathways and evaluates the likelihood of each potential exposure pathway. A further, effects-based screening step should be performed to identify any of the complete exposure pathways that are clearly unlikely to result in significant risk of harm to the environment. The two Stage I screening steps are described below in the following sections.

9.6.3.1 Identification of Complete Exposure Pathways

The risk assessor should consider all of the habitat types and receptors present in the affected area in order to identify exposure pathways of concern when a wetland has been affected by contamination. Exposure of aquatic organisms should be considered in submerged areas. Exposure of animals that periodically visit borders or banks of surface water bodies should also be considered. For upland areas in or adjacent to wetlands, the exposure pathways discussed in the Terrestrial Habitat section should be considered.

9.6.3.2 Effects-based Screening

Effects-based screening of contaminated wetland sediments may be done in the same way as screening of surface water sediment contamination, by comparing detected concentrations with NOAA's ER-Ls. The values on which the ER-Ls are based were derived from studies of both marine and freshwater sediments. The primary criterion for including a value in the development of the ER-Ls was the quality of the study rather than the freshwater or marine nature of the sediments evaluated. Despite the combination of freshwater and marine data, the ER-Ls are sufficiently protective to serve as screening criteria.

Effects-based screening of standing water in wetlands may be conducted in the same way as described for surface water in general, i.e., by comparing detected concentrations with Ambient Water Quality Criteria or the LOAELs published in the

Quality Criteria for Water (EPA 1986). The EPA Sediment Quality Criteria may also be applicable at some locations[22].

Many of these values are based on toxicity to a species that do not inhabit wetland areas, and they should not necessarily be used as benchmarks in quantitative wetland assessments. However, the values are considered sufficiently protective for use as wetland screening criteria.

If the risk of harm cannot be ruled out for any exposure pathway, an evaluation of that pathway by a Stage II Risk Characterization is necessary.

9.6.4 Stage II Environmental Risk Characterization

Potential assessment endpoints for wetlands include all of the conditions that have been discussed for both terrestrial or aquatic habitats. The sampling and analysis considerations and measurement methods discussed for other habitats are also applicable in wetland areas. As a consequence, this section is limited to a very brief discussion of considerations specific to wetland habitats.

The relative significance of various exposure pathways and the most sensitive species may differ from other habitats because of the unique structural and functional characteristics of wetlands. Wetlands are extraordinarily productive and biologically diverse habitats. They provide important nursery areas and primary habitats for many species. These functions are primary considerations in identifying receptors of concern and selecting assessment endpoints. For example, given that wetlands function as nurseries for a wide array of species, assessments should consider potential effects on early life stages, which may be more sensitive to toxins than later life stages.

Risk assessors should consider separately the risks to mammal, bird, reptile, amphibian and state-listed (rare) vertebrate and invertebrate species that spend a significant portion of their life cycle in or along water bodies, within the hundred year floodplain, or within any other wetland area. Although many animal species of concern in wetland habitats are also likely to be exposed in terrestrial or aquatic habitats, the exposure conditions are likely to be very different, and the relative impacts of the contaminants on various species may differ. For example, some amphibians are likely to receive higher exposures in wetlands than other habitats because they spend most

[22]The EPA Sediment Quality Criteria for non-polar organic compounds are based on toxic concentrations in surface water and are derived using sediment/water partitioning coefficients. Therefore, these criteria are only appropriate for wetland sediments that are permanently flooded.

of their time in wetland areas. Endangered species are also of particular concern, because wetlands are primary habitat area for a large proportion of that group.

Damage to ecological function is an impact which may have more serious implications for wetlands than for other habitats. Because high productivity and chemical and mineral recycling processes normally occur in wetlands, impairment or loss of these functions over a substantial wetland area would represent a significant risk of harm to the environment in the vicinity of the site.

9.7 APPLICABLE OR SUITABLY ANALOGOUS STANDARDS

The MCP states that a level of no significant risk of harm to the environment has not been achieved if concentrations of oil and hazardous material at or from the site exceed or are likely to exceed any applicable or suitably analogous standards, including Massachusetts Surface Water Quality Standards promulgated at 314 CMR 4.00, at current and reasonably foreseeable exposure points (310 CMR 40.0995(4)d.). When a site specific environmental risk characterization is employed, the cleanup decision may be driven by the results of the site-specific evaluation, by an exceedance of a standard, or by both.

For MCP Environmental Risk Characterizations, two sets of potentially applicable or suitably analogous standards have been identified. The first is the Massachusetts Surface Water Quality Standards, which are specifically cited as such in the MCP, as described in the preceding paragraph. The second are the Standards applied under the Wetlands Protection Act. These sets of standards are described in more detail in the following sections.

9.7.1 Massachusetts Surface Water Quality Standards

Massachusetts Surface Water Quality Standards are applicable to concentrations of oil and/or hazardous material in surface water. These standards are promulgated at 314 CMR 4.00, which gives numerical values for dissolved oxygen, temperature, pH, fecal coliform, solids, color and turbidity, oil and grease, and taste and odor. Narrative standards are set for aesthetics, bottom pollutants or alterations, nutrients, radioactivity and toxic pollutants.

9.7.1.2 Surface Water Standards for Toxic Pollutants

Of the narrative standards, the one for toxic pollutants is most relevant for oil and hazardous material releases from 21E sites. The text (314 CMR 4.05(5)(e)) is as follows:

(e) Toxic Pollutants - All surface waters shall be free from pollutants in concentrations or combinations that are toxic to humans, aquatic life or wildlife. Where the Division [of Water Pollution Control] determines that a specific pollutant not otherwise listed in 314 CMR 4.00 could reasonably be expected to adversely effect existing or designated uses, the Division shall use the recommended limit published by EPA pursuant to 33 USC 1251, 304(a) as the allowable receiving water concentration for the affected waters unless a site specific limit is established. The Division shall use the water quality criteria for the protection of aquatic life in terms of the dissolved fraction of metals. Recommended limits based on total recoverable metals may be converted to dissolved metals using factors recommended by EPA or methods approved by the Division. Recommended limits for metals may be modified by site-specific considerations. Site-specific limits, human health risk levels and permit limits will be established in accordance with the following:

1. *Site-specific limits: Where recommended limits for a specific pollutant are not available or where they are invalid due to site-specific physical, chemical or biological considerations, the Division shall use a site-specific limit as the allowable receiving water concentration of the affected waters. In all cases, at a minimum, site-specific limits shall not exceed safe exposure levels determined by toxicity testing using methods approved by the Director [of the Division of Water Pollution Control].*

2. *Human Health Risk Levels[23]: The human health-based regulation of toxic pollutants shall be in accordance with guidance issued by the Department of Environmental Protection's Office of Research and Standards. The Division's goal shall be to prevent all adverse health effects which may result from the ingestion, inhalation or dermal contact with contaminated waters during their reasonable use as designated in these regulations. When this goal is not attainable, the guidance will specify acceptable excess lifetime cancer risk levels for carcinogens and methodology to be used for their application. The Division [of Water Pollution Control] may also consider factors of practicability and feasibility when deriving effluent limitations from the human health-based criteria.*

[23]In environmental risk characterizations conducted under the MCP, human health considerations are not addressed. All potential human exposures are considered in human health risk characterizations. This section is included here to make the citation complete.

3. *Accumulation of Pollutants*[24]: *Where appropriate the Division [of Water Pollution Control] shall use an additional margin of safety when establishing water quality based effluent limits to assure that pollutants do not persist in the environment or accumulate in organisms to levels that: (a) are toxic to humans or aquatic life; or (b) result in unacceptable concentrations in edible portions of marketable fish or shellfish or for the recreational use of fish, shellfish , other aquatic life or wildlife for human consumption.*

4. *Public Notice: Where recommended limits or site-specific limits are used to establish water quality based effluent limitations they shall be documented and subject to full intergovernmental coordination and public participation as set forth in 314 CMR 2.00 "Permit Procedures".*

In the regulations cited above, the phrase "*the Division shall use the recommended limit published by EPA pursuant to Section 304 (a) of the Federal Act*" means that the EPA Ambient Water Quality Criteria (AWQC) are adopted as Massachusetts Surface Water Quality Standards. The derivation of these is documented in Quality Criteria for Water (EPA 1986, with updates). Note that only actual criteria are considered applicable standards. Quality Criteria for Water (EPA 1986) presents LOAELs for toxics for some substances for which criteria could not be developed due to insufficient data. However, those LOAELs are not considered applicable standards.

The EPA has published criteria for both the protection of aquatic life and for the protection of human health, but only the criteria for the protection of aquatic organisms are applicable standards for environmental risk characterization. The criteria that are based on drinking water and fish consumption are applicable standards for a human health risk characterization.

Application of the Ambient Water Quality Criteria requires site-specific consideration of hardness. The EPA Ambient Water Quality Criteria for cadmium, chromium III (trivalent chromium), copper, lead, mercury, nickel, silver, and zinc are all hardness-dependent. For a given aqueous concentration, toxicity increases as hardness decreases. In general the listed values are based on an assumed hardness of 100 mg/L, but hardness in Massachusetts water bodies typically runs about 25 mg/L. For a

[24]In an environmental risk characterization conducted under the MCP, accumulation of pollutants should be addressed in the site-specific exposure assessment separately from comparison of surface water concentrations to surface water standards.

standard to be protective at a specific site where hardness is lower than 100 mg/L, the listed values should be adjusted.

There are currently no limitations on the applicability of surface water standards established for the protection of aquatic life. Surface Water Standards apply to all surface water in the state. All surface water in Massachusetts is currently classified as:

A - public water supply
B - fishable/swimmable
SA - saltwater open shellfishing
SB - salt water restricted shellfishing

There is no surface water in the state in which aquatic life is explicitly not protected. Thus, surface water standards that protect aquatic life (marine and freshwater Ambient Water Quality Criteria) apply to all surface water bodies in Massachusetts.

9.7.2 Massachusetts Wetlands Regulations

The Massachusetts Wetlands Protection Act regulates alterations of wetlands with the objective of preserving and promoting certain public interests, which include: the protection of public or private water supplies and groundwater supplies, the enhancement of flood control and storm damage prevention, the prevention of pollution and the protection of fisheries and land containing shellfish. An amendment to the Act (St. 1986, c. 262) adds wildlife habitat to those interests. This section describes wetlands alterations resulting from contamination that represent violations of the Wetlands Protection Act, and would in effect constitute an exceedance of an applicable or suitably analogous standard. Exceedance of an applicable standard is *per se* indicative of "Significant Risk of Harm" to the environment for 21E purposes. Wetlands alterations indicative of "Significant Risk of Harm" include :

1. Contamination of inland wetlands resource areas which destroys or otherwise impairs any portion of **"Bordering Vegetated Wetland"** (as defined in 310 CMR 10.55(4)(a).

2. Contamination of inland wetlands resource areas within a **Bank** (as defined in 310 CMR 10.54) or **Land Under a Water Body or Waterway** (as defined in 310 CMR 10.56), which impairs ground water and surface water quality,, or the capacity of such areas to provide breeding habitat, escape cover and food for fisheries [10.56(4)(a)(2)&(3)].

3. Contamination of inland wetlands resource areas within **any inland resource area** subject to protection of the Wetlands Protection Act, which has a long or short term adverse effect on the habitat of the local population of a **"rare"** species listed by the DFWELE Natural Heritage and Endangered Species Program. The Heritage Program should be consulted to determine whether there is a substantial risk of such an adverse effect whenever contamination is in a location indicated as rare species habitat on that Program's most recent Estimated Habitat Map of State-listed Rare Wetlands Wildlife [10.53(3); 10.54(4)(c); 10.55(4)(d); 10.56(4)(c); and 10.57(4)(c)].

4. Contamination of Inland **Land Subject to Flooding** which has an adverse effect on **vernal pool habitat (in any inland resource area** subject to the Wetlands Protection Act) lasting greater than two years. The DFWELE Natural Heritage and Endangered Species Program should be consulted to determine whether there is a substantial risk of such an adverse effect whenever contamination is in a location indicated as vernal pool habitat on that Program's most recent Estimated Habitat Map of State-Listed Rare Wetlands Wildlife [10.57(4)(a)(3) and (b)(4)].

5. Contamination of inland wetlands resource areas which has an adverse effect, lasting greater than two years, on more than the following amounts of **non-rare wetland wildlife habitat**: 50 feet of **Bank** (as defined in 310 CMR 10.54); 5,000 sq. ft. of **Land Under Water** (as defined in 310 CMR 10.56); or 5,000 sq. ft. of **Bordering Land Subject to Flooding** (as defined in 310 CMR 10.57) located within the 10 year floodplain or within 100 feet of the bank or bordering vegetated wetland (whichever is further from the water body or waterway, so long as such area is contained within the 100 year floodplain) [10.54(4)(a)(5); 10.56(4)(a)(4); and 10.57(4)(a)(3)].

6. Contamination of any coastal wetland resource areas which, within **any coastal resource areas except any Designated Port Areas** (as defined in 310 CMR 10.26) subject to protection of the Wetlands Protection Act, has a long or short term adverse effect on the habitat of the local population of a **"rare"** species listed by the DFWELE Natural Heritage and Endangered Species Program. The Heritage Program should be consulted to determine whether there is a substantial risk of such an adverse effect whenever contamination is in a location indicated as rare species habitat on that Program's most recent Estimated Habitat Map of State-listed Rare Wetlands Wildlife [10.25(7); 10.27(7); 10.28(6); 10.29(4); 10.30(8); 10.31(5); 10.32(6); 10.33(5); 10.34(8); and 10.35(5)].

7. Contamination of any coastal wetland resource areas which destroys any portion of a **salt marsh** (as defined in 310 CMR 10.32) or has an adverse effect on its productivity (alterations in growth, distribution and composition of salt marsh vegetation shall be considered in evaluating adverse effects on productivity) [10.32(3)(a)].

8. Contamination of any coastal wetland resource areas which has an adverse effect on marine fisheries (including shellfish) or wildlife habitat of a **Salt Pond** (as defined in 310 CMR 10.33), **Land Under the Ocean** (as defined in 310 CMR 10.25) **Tidal Flat** (as defined in 310 CMR 10.27) or **Barrier Beach** (as defined in 310 CMR 10.29) by:

a. altering water quality (other than natural fluctuations in the level of dissolved oxygen, temperature or turbidity, or the addition of pollutants);

b. altering the productivity of plants (specifically eelgrass and widgeon grass beds on Land Under the Ocean Tidal Flats and Barrier Beaches); or

c. altering shallow submerged lands with high densities of polychaetes, mollusks or macrophytic algae (10.33(3); 10.25(6); 10.27(6) and 10.29(3)].

9. Contamination of any coastal wetland resource area which has an adverse effect by altering the productivity of **Land Containing Shellfish** (as defined in 310 CMR 10.34) through an alteration of water quality (including but not limited to, the elements listed under 8a, above) [10.34(4)];

10. Contamination of any coastal wetland resource area which has an adverse effect on anadromous or catadromous **Fish Runs** (as defined in 310 CMR 10.35) by impairing the capacity of spawning or nursery habitats necessary to sustain the various life stages of the fish [10.35(3)(c)];

11. Contamination of any coastal wetland resource area, within **Coastal Dunes or Barrier Beaches** (as defined in 310 CMR 10.28 and 10.29), which has an adverse effect on coastal dune by disturbing the vegetative cover so as to de-stabilize the dune, or by interfering with mapped or otherwise identified bird nesting habitat [10.28(3)(b)&(f) and 10.29(3)].

12. Contamination of any wetland resource area located within an inland or coastal ACEC which has an adverse effect on the resource area.

REFERENCES FOR SECTION 9.0

American Society for Testing and Materials 1990. *Standard Guide for Conducting Sediment Toxicity Tests with Freshwater Invertebrates.* ASTM E-1383-90.

Cowardin, L.M.; V. Carter; F.C. Golet; and E.T. La Roe (1979). *Classification of Wetlands and Deepwater Habitats of the United States.* U.S. Department of the Interior, Fish and Wildlife Services, Office of Biological Services. FWS/OBS-79/31.

Emlen, J.M. (1989). *Terrestrial Population Models for Ecological Risk Assessment: A State-of-the-Art Review.* Environmental Toxicology and Chemistry 8:831-842.

LaPoint, T.W. and Fairchild, J.F. (1988). *Aquatic Surveys.* In W. Warren-Hicks, B.R. Parkhurst and S.S. Baker (Ed.) Ecological Assessments of Hazardous Waste Sites. EPA 1988.

Long, E.R.; D.D. MacDonald; S.L. Smith; and F.D. Calder (1990). *Incidence of Adverse Biological Effects Within Ranges of Chemical Concentrations in Marin and Estuarine Sediments.* Environmental Management 19 (1): 81-97.

Lowrance, R. and G.Vellidis (1993). *Bottomland Hardwoods in the Tifton-Vidalia Upland of Georgia: A Conceptual Model for Ecological Risk Assessment. Final Project Report to U.S.EPA Wetlands Research Program* EPA/600/R-93/186 September.

MacDonald, DD. (1992). *Development of an Integrated Approach to the Assessment of Sediment Quality in Florida.* Prepared for Florida Department of Environmental Regulation. McDonald Environmental Services, Ltd. Ladysmith, British Columbia.

McBee, K. (1988). *Field Surveys: Terrestrial Vertebrates.* In W. Warren-Hicks, B.R. Parkhurst and S.S Baker (Ed.) Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document. EPA 1988.

Menzie, C.A.; D.E. Burmaster; J.A. Freshman; and C.A. Callahan (1992). *Assessment of Methods for Estimating Ecological Risk in the Terrestrial Component: A Case Study at the Baird & McGuire Superfund Site in Holbrook, Masssachusetts. Environmental Toxicology and Chemistry*, 11: 245-260.

Preston, E.M. and B.L. Bedford. 1988. *Evaluating Cumulative Effects on Wetlands Functions. A Conceptual Overview and Generic Framework*, Environmental Management 12:565-583.

National Oceanographic and Atmospheric Administration (1991). *The Potential for Biological Effects of Sediment-Sorbed Contaminants Tested in the National Status and Trends Program.* NOAA Technical Memorandum NOS OMA 52.

Suter, G. (1988). *Ecological Endpoints.* In Warren-Hicks, B.R. Parkhurst and S.S. Baker, Jr. (Ed.) Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document. EPA 1988.

Warren-Hicks, W.; B.R. Parkhurst; and S.S. Baker (1988). *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document.* EPA 1988.

U.S. Environmental Protection Agency (1986). *Quality Criteria for Water.*

U.S. Environmental Protection Agency (1988). *Interim Sediment Criteria for Non-Polar Hydrophobic Organic Contaminants.* Office of Water Regulations and Standards, Criteria and Standards Division.

U.S. Environmental Protection Agency, Region I (1989). *Guidance for Ecological Risk Assessments, Draft Final.*

U.S. Environmental Protection Agency (1989a). *Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual.*

U.S. Environmental Protection Agency (1989b). *Short-term Methods for Estimating Chronic of Effluents and Receiving Waters to Freshwater and Marine Organisms.*

U.S. Environmental Protection Agency (1989c). *Terrestrial Ecosystem Exposure Assessment Model (TEEAM).* EPA/600/3-88/038.

U.S. Environmental Protection Agency (1990). *Criteria for Choosing Indicator Species for Ecological Risk Assessments at Superfund Sites.* (90-6402) PB91-204321. Prepared by North Carolina University at Chapel Hill.

U.S. Environmental Protection Agency (1991). *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms.* EPA/600/4-90/027.

U.S. Environmental Protection Agency (1992a). *Framework for Ecological Risk Assessment.* EPA/630/R-92/001.

U.S. Environmental Protection Agency (1992b). *Sediment Classification Methods Compendium.* EPA823-R-92-006.

U.S. Environmental Protection Agency (1993). *Interim Report on Data and Methods for Assessment of 2,3,7,8 - Tetrachlorodibenzo-p-dioxin Risks to Aquatic Life and Associated Wildlife*. EPA/600/R-93/055. March 1993.

U.S. Environmental Protection Agency (1993). *Wildlife Exposure Factors Handbook*. EPA/600/R-93/187b.

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